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Washington, Saturday, December 30, 1950

TITLE 3—THE PRESIDENT

PROCLAMATION 2915

AMENDING PROCLAMATION NO. 2906[1] OF OCTOBER 6, 1950, ENTITLED "SPECIAL REGISTRATION"

BY THE PRESIDENT OF THE UNITED STATES OF AMERICA

A PROCLAMATION

WHEREAS I find such action to be practicable and desirable, in the interest of the national defense, and in the national interest:

NOW, THEREFORE, I, Harry S. Truman, President of the United States of America, acting under and by virtue of the authority vested in me by the Selective Service Act of 1948, as amended, and as President of the United States, hereby proclaim that Proclamation No. 2906 of October 6, 1950, be, and it is hereby, amended, effective as of October 6, 1950, so as to exempt from the force and effect thereof, until otherwise directed by the President by proclamation, (1) commissioned officers, warrant officers, pay clerks, enlisted men, and aviation cadets of the Regular Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, the Coast and Geodetic Survey, and the Public Health Service, and (2) aliens who are residing in the United States and have not declared their intention of becoming citizens of the United States and who are also in one of the following categories: (a) alien students admitted under subdivision (e) of section 4 of the Immigration Act approved May 26, 1924, as amended, (b) aliens recognized as diplomatic, consular, military or civilian officials or employees of a foreign government and members of their families, (c) aliens who are officials or employees of a public international organization recognized under the International Organizations Immunities Act, approved December 29, 1945 (59 Stat. 669), and members of their families, (d) aliens who have entered the United States and remain therein pursuant to the provisions of section 11 of the Agreement between the United Nations and the United States of America regarding the Headquarters of the United Nations, as approved in Public Law 357, 80th Congress (61 Stat. 756), (e) aliens who are nationals of a country with which there is in effect a treaty or international agreement exempting its nationals from military service while they are within the United States, or (f) other aliens whose admission to the United States is for a temporary stay only: *Provided*, that such exemption shall not continue after the cause thereof shall cease to exist.

The said proclamation of October 6, 1950, is hereby further amended by substituting for the words "doctor(s) of medical dentistry" wherever they occur therein, the words "doctor(s) of dental medicine."

IN WITNESS WHEREOF, I have hereunto set my hand and caused the Seal of the United States of America to be affixed.

DONE at the City of Washington this 27th day of December in the year of our Lord nineteen hundred and fifty, and of the Independence of the United States of America the one hundred and seventy-fifth.

[SEAL]

HARRY S. TRUMAN

By the President:

DEAN ACHESON,
Secretary of State.

[F. R. Doc. 50-12592; Filed, Dec. 28, 1950; 3:47 p. m.]

[1] 15 F. R. 6845.

TITLE 5—ADMINISTRATIVE PERSONNEL

Chapter I—Civil Service Commission

PART 6—EXCEPTIONS FROM THE COMPETITIVE SERVICE

MISCELLANEOUS AMENDMENTS

1. Under authority of § 6.1 (d) of Executive Order 9830, the exception of the position of "Chief, Reports Analysis Branch" in the Office of Loans, Reconstruction Finance Corporation (§ 6.121 (h) (1) is revoked, effective upon publication in the FEDERAL REGISTER.

2. Effective upon publication in the FEDERAL REGISTER, § 6.103 (h) (2) is amended to read as follows:

§ 6.103 *Treasury Department.* * * *
(h) *Comptroller of the Currency.*
* * *

(Continued on p. 9422)

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THE PRESIDENT

EXECUTIVE AGENCIES

FEDERAL REGISTER

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CODIFICATION GUIDE

A numerical list of the parts of the Code of Federal Regulations affected by documents published in this issue. Proposed rules, as opposed to final actions, are identified as such.

CODIFICATION GUIDE—Con.

(2) NC/PD. Until December 31, 1951, positions of Chief National Bank Examiner, Assistant Chief National Bank Examiner, District Chief National Bank Examiner, National Bank Examiner, and Assistant National Bank Examiner, whose salaries are paid from assessments against national banks and other financial institutions.

3. Effective upon publication in the FEDERAL REGISTER, § 6.107 (b) (1) is amended to read as follows:

§ 6.107 *Department of the Air Force.* * * *

(b) *Office of the Inspector General.* (1) Until December 31, 1951, in order to provide civilian personnel complementary to military personnel, 20 Special Agent positions in the Office of Special Investigations, Office of the Inspector General, Headquarters, and 75 Special Agent positions in district offices of the Office of Special Investigations, U. S. Air Force, in grades GS–11 or higher.

4. Effective upon publication in the FEDERAL REGISTER, § 6.120 (b) is amended to read as follows:

§ 6.120 *The Tax Court of the United States.* * * *

(b) NC/PD. Until December 31, 1951, a Clerk of the Court and a Chief Deputy Clerk.

5. Effective upon publication in the FEDERAL REGISTER, § 6.121 (h) is amended to read as follows:

§ 6.121 *Reconstruction Finance Corporation.* * * *

(h) *Office of Loans.* (1) Until December 31, 1951, positions of Manager; Assistant Manager; Executive Assistant to the Manager; Chairman and four members of the Review Committee; Chairman and Vice Chairman, Committee on Practices and Procedures; Chairman and Vice Chairman, Marketing and Liquidation Committee; Director and Assistant Director each of the Loan Operations and Field Operation Division; Chief and Assistant Chief, each of the Public Agency and Field Liaison Branches; Chief and two Assistant Chiefs of the Business Loans Branch; Chief of the Mining Branch; Chief of the Transportation Branch; Chief of the Financial Institutions Branch; Chief Engineer and Chief Appraiser of the Engineering and Appraisal Branch; Head of the Railroad Section; and Head of the Air, Motor, and Marine Section.

6. Effective upon publication in the FEDERAL REGISTER, § 6.142 (c) (7) is amended to read as follows:

§ 6.142 *Housing and Home Finance Agency.* * * *

(c) *Federal Housing Administration.* * * *

(7) NC/PD. Until December 31, 1951, eighty Field Directors (State, District, and Territorial).

(R. S. 1753, sec. 2, 22 Stat. 403; 5 U. S. C. 631, 633. E. O. 9830, Feb. 24, 1947, 12 F. R. 1259; 3 CFR, 1947 Supp. E. O. 9973, June 28, 1948, 13 F. R. 3600; 3 CFR, 1948 Supp.)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] L. A. MOYER,
Executive Director.

[F. R. Doc. 50-12520; Filed, Dec. 29, 1950; 8:53 a. m.]

TITLE 7—AGRICULTURE

Chapter I—Production and Marketing Administration (Standards, Inspections, Marketing Practices), Department of Agriculture

Subchapter C—Regulations and Standards Under the Farm Products Inspection Act

PART 53—MEATS, PREPARED MEATS, AND MEAT PRODUCTS (GRADING, CERTIFICATION AND STANDARDS)

REVISION OF OFFICIAL U. S. STANDARDS FOR GRADES OF SLAUGHTER CATTLE

On November 29, 1950, there appeared in the FEDERAL REGISTER (15 F. R. 8166) a notice of proposed revision of the Official U. S. Standards for Grades of Slaughter Cattle (U. S. D. A., PMA, Service and Regulatory Announcement No. 112) under sections 203 and 205 of the Agricultural Marketing Act of 1946 (7 U. S. C. 1622 and 1624) and the items for marketing farm products and market inspection of farm products recurring in the annual appropriation acts for the Department of Agriculture and currently found in the Department of Agriculture Appropriation Act, 1951 (Chapter VI, Pub. Law 759, 81st Congress, 7 U. S. C. Supp. 414).

After due consideration of all relevant material presented pursuant to the notice and pursuant to the statutory authorities cited above, it is hereby ordered that said standards are revised to appear in 7 CFR, Part 53, Subpart C as follows:

SUBPART C—LIVE ANIMAL STANDARDS

Sec.
53.201 Cattle.
53.202 Slaughter cattle classes.
53.203 Slaughter cattle grades.
53.204 Specifications for official United States standards for grades of slaughter steers, heifers, and cows.
53.205 Specifications for official United States standards for grades of slaughter bulls.
53.206 Specifications for official United States standards for grades of slaughter stags.

AUTHORITY: §§ 53.201 to 53.206 issued under sec. 205, 60 Stat 1090, Pub. Law 759, 81st Cong.; 7 U. S. C. 1624. Interpret or apply sec. 203, 60 Stat. 1087; 7 U. S. C. 1622.

§ 53.201 *Cattle.* The official standards for live cattle developed by the United States Department of Agriculture provide for segregation first according to use—slaughter, feeder and stocker—then as to class which is determined by sex condition, and then as to grade which is determined by the apparent relative excellence and desirability of the animal for its particular use.

§ 53.202 *Slaughter cattle classes.* The classes of slaughter cattle are steers, heifers, cows, bulls and stags. Definitions of the respective classes are as follows:

(a) *Bull.* A bull is an uncastrated male bovine.

(b) *Steer.* A steer is a male bovine castrated when young and prior to developing the secondary physical characteristics of a bull.

(c) *Stag.* A stag is a male bovine castrated after it has developed or begun to develop the secondary physical characteristics of a bull.

(d) *Cow.* A cow is a female bovine that has developed through reproduction or with age, relatively prominent hips, a large middle, and other physical characteristics typical of mature females.

(e) *Heifer.* A heifer is an immature female bovine that has not developed the physical characteristics typical of cows.

§ 53.203 *Slaughter cattle grades*—(a) *Grade factors.* The specific grade of a slaughter animal is determined by an evaluation in terms of factors which influence carcass excellence—conformation, finish, quality and maturity.

(1) Conformation refers to the general body proportions of the animal and to the ratio of meat to bone. While primarily determined by the inherent muscular and skeletal system, it is also influenced by degree of fatness. Excellent conformation in slaughter cattle is denoted by a compact, wide topped, square rumped, and full quartered individual that is thickly fleshed. Fullness and thickness should be especially evident in the portions of the body producing the more desirable cuts of meat—loin, ribs, and rounds.

(2) Finish refers to the fatness of the animal. The quality, quantity and distribution of finish of the slaughter animal are very closely associated with the palatability and quality of the meat which it will produce. Thus finish becomes the most important single factor affecting the grade of slaughter cattle. External finish is evidenced by fullness and the apparent thickness of the fat covering over the back, loin, rump, ribs, and rounds. Also, fat deposits giving fullness to the brisket, rear flanks and cod or udder, while varying decidedly with the breeding of the animal, are useful indicators of internal finish. A high degree of desirable finish is evidenced by a thick, firm, smooth layer of fat which is uniformly distributed over the body.

(3) Quality in the live slaughter animal refers to the refinement of hair,

hide and bone and to the smoothness and symmetry of the body. Quality is also closely associated with carcass yield and the proportion of meat to bone. A high degree of quality in slaughter cattle is denoted by smoothness of fleshing, relatively small bones, neat joints, neatly laid in shoulders and hips, refined hair and thin pliable hide.

(4) The degree of maturity of slaughter cattle is appraised on the basis of the physical characteristics indicating age. Youthfulness and fatness of the slaughter animal are each credited with having a desirable effect on the palatability of meat. Therefore, within certain limits, the standards for slaughter cattle allow an increase in finish to compensate for advancing degrees of maturity.

(b) *General principles.* (1) The determination of the carcass grade that the live animal will produce requires the exercising of well regulated judgment. Each animal graded presents a different combination of the grade determining factors. It is not unusual to find an animal of one grade that has some of the characteristics associated with another grade or grades. Therefore, a composite evaluation of the total inherent physical characteristics of the animal is essential for accuracy in determining grade.

(2) Since evidences of maturity in the beef carcass vary among animals of the same approximate age, only general age limitations can be used for descriptive standards for slaughter cattle. Approximate maximum age limitations for steer, heifer and cow grades follow: Prime—36 months; Choice—42 months; and Good—48 months. There are no age limitations for the Commercial, Utility, Cutter or Canner grades.

(3) The designation of slaughter cattle grades is usually made by classes. Since the same standard is applied to carcasses from steers, heifers and cows without class identification, these three classes are also combined in the slaughter cattle grade descriptions. However, bulls and stags are always identified as to class in both carcass and slaughter cattle grading, since meat from these classes is never interchangeable with meat carrying the same grade name from steers, heifers and cows.

(4) The descriptions of the physical characteristics of the grades of slaughter cattle in §§ 53.204, 53.205, and 53.206 represent the lower limit of each grade. No attempt is made to describe the numerous combinations of grade factors which may meet the minimum requirements for a particular grade. Descriptions are limited largely to animals considered as typical of the lower limits of the grade.

§ 53.204 *Specifications for official United States standards for grades of slaughter steers, heifers, and cows*—(a) *Prime.* Only steers and heifers are eligible for the Prime grade. Cattle possessing the minimum qualifications for Prime grade are definitely superior in conformation, quality and finish. However, individual animals may differ somewhat in appearance because of possible variations in the degree of excellence of the individual grade factors. In conformation, Prime cattle tend to be low set, compact, thickly fleshed and short of neck and body. They are wide over the back and loin with the width carried out squarely into the rump. The shoulders and hips are neatly laid in and smooth. The twist is deep and full and the rounds thick and plump. There is a pronounced fullness or bulging over the crops, loin, and rump which contributes to a full, smooth, well-rounded appearance. The fat covering is firm. Steers and heifers over 30 months of age have a very thick covering of fat over the crops, back, ribs, loin and rump. The brisket, rear flanks and cod or udder are very full and distended. Although the finish is usually evenly distributed and smooth, some cattle may have rolls of fat over the ribs, and patches around the tailhead. Steers and heifers 18 to 30 months of age have a thick fat covering over the back, ribs, loin and rump. The brisket, rear flanks and cod or udder have the appearance of being filled and distended with fat. The fat covering tends to be smooth with only slight indications of patchiness. Steers and heifers under 18 months of age may have only a moderately thick but smooth covering of fat which extends over the back, ribs, loin and rump. The brisket, rear flank and cod or udder show a marked fullness. Prime cattle exhibit evidences of high quality. The bones tend to be proportionately small, joints smooth, the hide moderately thin and pliable, and the body trim, smooth and symmetrical. However, some cattle may show slight evidences of coarseness such as heavy bone, thick hide, and uneven distribution of fat.

(b) *Choice.* Cattle possessing the minimum qualifications for Choice grade may differ considerably in appearance because of the many possible combinations of varying degrees of excellence of the grade factors. In conformation, Choice cattle tend to be moderately low-set and compact. They are moderately thick in natural fleshing and are moderately wide over the back and loin. The shoulders and hips are moderately neat and smoothly laid in with only a slight tendency toward prominence in older cattle. The twist and rounds are of moderate depth and plumpness. There is a fullness or bulge distinctly evident over the crops, loin and rump. The distribution of fat may be slightly uneven, as evidenced by ties, rolls of fat over the loin edge and ribs, and patchiness around the tailhead. Cattle over 30 months of age have a thick covering of fat over the crops, back, ribs, loin and rump. The brisket, rear flank and cod or udder are well filled and distended. Cattle 18 to 30 months of age carry a moderately thick fat covering over the crops, back, loin, rump and down over the ribs. The brisket, rear flank and cod or udder show a marked fullness. Cattle under 18 months of age carry a slightly thick fat covering over the top. The brisket, rear flanks, and cod or udder appear moderately full. Choice cattle usually have a moderately refined appearance but some coarseness may be evident in older animals.

(c) *Good.* Cattle possessing minimum qualifications for Good grade may differ somewhat in appearance because of the numerous possible combinations of varying degrees of excellence of the grade factors. In conformation, Good cattle tend to be slightly low set and compact. They are slightly thick in natural fleshing and slightly wide over the back and loin. The shoulders and hips are usually moderately neat and smoothly laid in but may appear slightly prominent in older cattle. The twist and rounds are usually moderately deep but may appear slightly flat with very little evidence of plumpness. There is usually a very slight fullness evident over the crops, loin and rump. The distribution of fat may be somewhat uneven, particularly in older cattle, as evidenced by ties, rolls of fat over the loin edge and ribs, and patchiness about the tailhead. Cattle over 30 months of age carry a slightly thick covering of fat and the brisket, rear flanks and cod or udder show a marked fullness. Good cattle 18 to 30 months of age carry a slightly thin fat covering with some fullness evident in the crops, brisket, flanks and cod or udder. Cattle under 18 months of age may have somewhat limited finish which is largely restricted to the back, loin, and upper rib. The brisket, rear flanks, and cod or udder are slightly full. Good cattle are usually moderately smooth, and slightly refined in appearance. Some coarseness may be evident in the relatively older cattle of the Good grade.

(d) *Commercial.* Cattle possessing the minimum qualifications for Commercial grade may be highly variable in appearance because of the wide range in the possible combinations of age, conformation, finish and quality. The Commercial grade includes all ages of steers, heifers, and cows. Young cattle in this grade tend to be slightly rangy, upstanding, thin fleshed, narrow through the crops, back and loin, somewhat prominent at the hips and shallow in the twist and quarter. The loin, rump, and rounds appear flat with no evidence of fullness. Such cattle may show the heavy bone, prominent hips and shoulders associated with coarseness or they may show the small bones, tight hide and angularity denoting over-refinement. Cattle which range in age from 30 to 48 months carry a slightly thin covering of fat which is in evidence over the back, loin and ribs. The brisket, rear flanks, and cod or udder appear only slightly full. Cattle under 30 months of age carry only a thin covering of fat which is largely restricted to the back, loin, and upper rib. Fully mature cattle appear slightly rangy, upstanding, and somewhat thin fleshed. They appear deep through the fore-rib and moderately wide over the back and loin. The hips and shoulders are prominent, and the quarters thin and shallow with no apparent bulge or fullness. Cattle considered as having just reached full maturity carry a slightly thick fat covering over the back, ribs, loin, and rump which increases progressively with increasing age. Considerable patchiness about the tailhead may be evident. The crops, brisket, flanks and cod or udder appear slightly full. Mature Commercial cattle tend to be rather coarse and rough with

prominent shoulders and hips, slightly coarse bone, and moderately thick, heavy hides.

(e) *Utility.* Cattle possessing the minimum requirements of the Utility grade may vary greatly in appearance because of the numerous possible combinations of grade factors and the wide range in age of animals. In conformation, cattle of Utility grade tend to be rangy, upstanding, angular and thinly fleshed. They are usually narrow through the crops with a slightly sunken or hollowed-out appearance of the loin, rump and rounds. Shoulders and hips are decidedly prominent. Depth through the fore-rib is much greater than through the rear flank with a resulting low proportion of hindquarter. Mature cattle carry a slightly thick fat covering which may be restricted to the back, loin, and rump. The crops of these cattle are very thin, and the brisket, rear flanks and cod or udder show only very slight fullness. Progressively less finish is apparent in younger cattle ranging down to a very thin covering of fat for those under 30 months of age. Utility cattle tend to be of slightly low quality. The bones and joints are usually proportionately large and the hide either thick or tight and inelastic.

(f) *Cutter.* Cattle possessing minimum qualifications for Cutter grade may vary slightly in appearance because of age and varying combinations of grade factors. They tend to be decidedly inferior in conformation and quality and carry a very small amount of finish. Cutter cattle are very angular and rough in conformation. The fleshing is very thin, the hips and shoulders are very prominent, and the loin and rounds usually present a very sunken or hollowed-out appearance. Fully mature cattle carry only a very thin fat covering while young immature cattle show no indications of any fat covering. Cutter cattle are usually of low quality, appearing quite rough, coarse and unsymmetrical.

(g) *Canner.* Cattle of the Canner grade are normally those of advanced age and so extremely thin as to appear emaciated. The typical Canner animal appears extremely angular, long and thin of neck, extremely narrow and shallow bodied. Shoulders and hips are extremely prominent. Cattle of this grade are very thin fleshed and the outline of the bony framework is very evident. The loin, rump, and rounds present an extremely sunken and hollowed-out appearance. The general appearance denotes low quality. The relative proportion of meat to bone is quite low, joints appear large and the body is extremely angular and unsymmetrical.

§ 53.205 *Specifications for official United States standards for grades of slaughter bulls*—(a) *Choice.* Choice grade represents a very select segment of the class and is composed primarily of bulls that have not reached full maturity. Bulls possessing minimum qualifications for the Choice grade tend to be lowset, compact, blocky individuals that are very wide topped and very thickly fleshed. The neck, shoulders and rounds show pronounced thickness, yet they present a well-balanced, symmetrical, smooth appearance. While Choice bulls yield a moderately high proportion of loins, ribs and rounds, the development of the forequarters definitely exceeds that of the hindquarters. Choice bulls have a firm, relatively thick covering of fat which is fairly uniform and smooth. The brisket, rear flank, and twist appear full and plump. The appearance is neat and trim though some coarseness about the head and shoulders may be evident. The hide is pliable and of medium thickness. The bones and joints are moderately refined.

(b) *Good.* Good grade bulls include a wide range of ages and numerous combinations of the grade factors. In conformation, bulls meeting minimum qualifications for the Good grade tend to be moderately blocky and compact. They are thickly fleshed with short, thick necks, moderately wide backs and loins, and moderately thick rounds. Young bulls of this grade have only a slightly thick covering of fat. Older bulls carry at least a moderately thick fat covering with noticeable fullness in the brisket, rear flanks and twist. Bulls of this grade show only moderate refinement. They usually appear somewhat coarse in the shoulders and heavy of bone and have slightly thick hides.

(c) *Commercial.* Bulls possessing minimum qualifications for Commercial grade are somewhat angular and rangy. They usually lack width and thickness over the top but appear rather thick through the neck, shoulders, and rounds. Yearling bulls have a very thin fat covering and older bulls appear slightly thin. The brisket and rear flanks appear only slightly full. Bulls of the Commercial grade are usually of rather low quality. They are usually coarse boned, prominent in the shoulders, and lacking generally in body symmetry.

(d) *Utility.* Bulls possessing minimum qualifications for Utility grade are usually inferior in conformation and quality and very deficient in finish. Bulls of this grade are upstanding, rangy, narrow topped, and very shallow of twist and round. They are thinly fleshed but appear slightly thick through the shoulders and rounds. Young bulls of this grade are practically devoid of finish, while older bulls have a very thin covering of fat. Exterior fats are confined principally to the back and the region about the tailhead. There is little or no evidence of fat deposits in the brisket or rear flank. Utility bulls are very coarse and rough in appearance, being especially prominent in the shoulders and hips, and lacking decidedly in trimness and body symmetry.

(e) *Cutter.* Bulls possessing minimum qualifications for Cutter grade are extremely inferior in conformation and quality and practically devoid of finish. They tend to be very upstanding, rangy and angular, thinly fleshed, narrow and shallow bodied. Shouders and hips are very prominent and the loin, rump and round present a rather sunken or hollowed-out appearance. The brisket is usually very wrinkled with no evidence of fullness.

(f) *Canner.* Typical Canner grade bulls are very angular and rangy and so extremely thin as to appear emaciated. The muscular portions of the body present a sunken or hollowed-out appearance and the outline of the bony framework is very prominent and visible. Bulls of this grade possess an extremely low proportion of meat to bone.

§ 53.206 *Specifications for official United States standards for grades of slaughter stags*—(a) *Choice.* Stags possessing minimum qualifications for Choice grade tend to be lowset, compact, wide, and deep of body. They are thickly fleshed with pronounced thickness of the neck, shoulders and rounds. Although yielding a relatively high proportion of ribs, loins and rounds, the forequarters are decidedly deeper and thicker and show more development than the hindquarters. Choice stags usually show evidences of not being fully mature and carry a firm relatively thick covering of fat. The brisket, flanks and cod tend to be full and distended. Stags of this grade are usually smooth in their finish but are of only moderate quality. They show some coarseness about the head and neck, slight prominence of the shoulders, fairly large bones and joints, and moderately thick but pliable hides.

(b) *Good.* Stags possessing minimum qualifications for Good grade tend to be moderately compact and thick in appearance. The neck is usually short and very thick and the shoulders wide, somewhat prominent and thickly fleshed. The back, loin, and rump are only moderately wide and full while the rounds appear thick and plump. Stags of this grade usually are much deeper and heavier through the forequarters than in the hindquarters. Relatively young stags have a slightly thick fat covering, while older stags have at least a moderately thick finish. The fat covering is fairly smooth and extends evenly over the crops, back and loin but may be slightly thin over the lower rib, rounds and shoulders. The brisket, flanks and cods appear moderately full. Stags of this grade appear rather coarse and lacking generally in refinement.

(c) *Commercial.* Stags possessing minimum qualifications for Commercial grade are usually upstanding, rangy and narrow. They are very thick through the neck and shoulders. They may be slightly thinly fleshed and the back, loin and rump may appear slightly thin and lacking in fullness. The rounds are moderately thick but shallow and lacking in plumpness. Relatively young stags have a thin covering of fat, while older stags have a slightly thick covering and usually show some fullness in the brisket and cod. Stags of this grade are usually rough, with prominent shoulders and heavy forequarters, and are very unsymmetrical in appearance.

(d) *Utility.* Stags possessing minimum qualifications for Utility grade are very upstanding, long and shallow of body, and very narrow and uneven over their top. The neck and shoulders are moderately thick, while the back, loin and rump have a thin, depressed or hollowed-out appearance. The depth of body is much greater through the fore rib than through the rear flank, with a resulting low proportion of hindquarter. The fat covering of Utility stags is thin and confined mostly to the back and loin,

with the lower part of the shoulders, ribs and rounds being practically devoid of finish. The quantity of finish may range from very thin for very young stags to only slightly thick for old mature stags. Utility stags are decidedly rough and coarse in appearance. Coarseness is very evident in the head, neck, shoulders, hips, and heavy bone.

(e) *Cutter.* Stags possessing minimum qualifications for the Cutter grade are inferior in conformation and quality, and very deficient in finish. They appear very angular and very narrow throughout. They are very thinly fleshed and carry only a very thin to extremely thin covering of fat. The fleshy portions of the body have a sunken or hollowed-out appearance and the shoulders and hips are very prominent. The proportion of ribs, loins and rounds from Cutter stag carcasses is relatively low.

(f) *Canner.* Typical Canner grade stags are extremely inferior in conformation and quality and practically devoid of finish. In conformation, they appear extremely angular, rangy, narrow and shallow. They are extremely thin fleshed, and the outline of the bony framework of the animal's body is evident. Loins and rounds appear very sunken and hollowed-out. The relative proportion of meat to bone is extremely low, joints and bones appear large, and the body is very unsymmetrical.

Present Subpart B of Part 53, Title 7, Code of Federal Regulations, is hereby redesignated as "Subpart B—Carcass Standards."

This order shall become effective upon publication in the FEDERAL REGISTER.

This order conforms the slaughter cattle standards with revised standards for grades of carcass beef which are to become effective on December 29, 1950. It is desirable that these standards become effective as nearly concurrently as possible to avoid in so far as possible a variance between the criteria for determining the class and quality of slaughter cattle and the criteria for making similar determinations for carcass beef derived from such cattle. Accordingly good cause is found under section 4 of the Administrative Procedure Act (5 U. S. C. 1003) for issuance of this order effective less than 30 days after its publication in the FEDERAL REGISTER.

Done at Washington, D. C., this 29th day of December, 1950.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12463; Filed, Dec. 29, 1950; 10:48 a. m.]

PART 70—GRADING AND INSPECTION OF POULTRY AND DOMESTIC RABBITS AND EDIBLE PRODUCTS THEREOF; UNITED STATES SPECIFICATIONS FOR CLASSES, STANDARDS AND GRADES WITH RESPECT THERETO

GRADING AND INSPECTION PROGRAMS AND SERVICES

On December 13, 1950, notice of a proposed amendment to the regulations governing the grading and inspection of poultry and domestic rabbits and edible products thereof and United States specifications for classes, standards, and grades with respect thereto (7 CFR Part 70) was published in the FEDERAL REGISTER (15 F. R. 8827). The amendment hereinafter set forth will extend, until May 1, 1951, the period of exemption of dressed poultry and dressed domestic rabbits, as such, from the provisions of §§ 70.16 and 70.17 of the regulations. This amendment is deemed necessary because of the shortage of materials needed to bring poultry processing plants into compliance with § 70.16 of the regulations. The poultry processing trade has requested the proposed extension to enable poultry dressing plants to complete the requisite changes in facilities without undue hardship; and no written data, views, or arguments were submitted, during the period prescribed therefor, for consideration by the Department with respect to this action.

The regulations currently provide that after December 31, 1950, only dressed poultry and dressed domestic rabbits which are produced in official plants may be brought into other official plants for processing under grading or inspection service. In order that those plants which are currently operating under the services provided for in the aforesaid regulations may continue to operate without interruption and in view of the current scarcity of necessary materials, it has been determined that the amendment set forth herein be made effective upon publication in the FEDERAL REGISTER. Furthermore, the amendment relieves restrictions against the handling of dressed poultry and dressed domestic rabbits, as such.

The regulations are hereby amended by revising the heading and provisions of § 70.3 (h), *Exemption for one year from the provisions of § 70.16 and § 70.17* to read as follows:

§ 70.3 *Grading and inspection programs and services.* * * *

(h) *Exemption from the provisions of §§ 70.16 and 70.17.* The provisions of §§ 70.16 and 70.17 shall not become applicable to the production of dressed poultry and dressed domestic rabbits, as such, until May 1, 1951. Prior to this date, dressed poultry and dressed domestic rabbits which have been produced in other than official plants may be brought into official plants for grading, inspection, or processing thereof. On and after May 1, 1951, only dressed poultry and dressed domestic rabbits from an official plant may be brought into another official plant for grading, inspection, or processing thereof.

(Sec. 205, 60 Stat. 1090, Pub. Law 759, 81st Cong.; 7 U. S. C. 1624. Interprets or applies sec. 203, 60 Stat. 1087; 7 U. S. C. 1622)

Issued at Washington, D. C., this 27th day of December 1950.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12579; Filed, Dec. 29, 1950; 8:56 a. m.]

Chapter VIII—Production and Marketing Administration (Sugar Branch), Department of Agriculture

Subchapter B—Sugar Requirements and Quotas

[Sugar Reg. 813]

PART 813—SUGAR QUOTAS AND PRORATIONS OF QUOTA DEFICITS

QUOTAS AND DEFICITS, 1951

By virtue of the authority vested in the Secretary of Agriculture by the Sugar Act of 1948 (61 Stat. 922) and the Administrative Procedure Act (60 Stat. 237), the regulations of this part are hereby made, prescribed and published to be in force and effect for the calendar year 1951 or until amended or superseded by regulations hereafter made during the calendar year 1951.

Basis and purpose. The sugar quotas set forth below have been established pursuant to section 202 of the Sugar Act of 1948 (hereinafter called the "act") in terms of short tons of sugar, raw value, equal to the quantity determined by the Secretary of Agriculture to be needed to meet the requirements of consumers in the continental United States for the calendar year 1951. The purpose of Sugar Regulations 813 is to establish quotas representing the quantities of sugar which the producing areas may supply to the continental United States market during the calendar year 1951. Prior to the issuance of this regulation, notice was given (15 F. R. 7526) that the Secretary of Agriculture was preparing, among other things, to establish sugar quotas for the calendar year 1951 and to determine whether any domestic area, the Republic of the Philippines, or Cuba would be unable to market the full quota for such area in 1951 and to reallot any quota deficit so determined. In accordance with the Administrative Procedure Act (60 Stat. 237), due consideration has been given to the data, views and arguments submitted in writing by interested persons and to the data, views and arguments expressed at the public hearing held on November 28, 1950, in Washington, D. C., for the purpose of affording interested persons an opportunity to express their views with respect to the establishment of sugar quotas for the calendar year 1951.

Since the sugar quotas for some areas are relatively small, thereby making it possible for such areas to exceed their quotas within a few days after the beginning of the quota year, it is not possible to comply with the 30-day effective date requirement of the Administrative Procedure Act. Accordingly, § 813.21 through § 813.28 will become effective January 1, 1951.

Sec.
813.21 Basic quotas for domestic areas.
813.22 Basic quotas for other areas.
813.23 Determination and proration of area deficits.
813.24 Proration of quota for foreign countries other than Cuba and the Republic of the Philippines.
813.25 Direct-consumption portion of quotas or prorations.
813.26 Liquid sugar quotas.
813.27 Restrictions on marketing and shipment.
813.28 Inapplicability of quota regulations.

AUTHORITY: §§ 813.21 to 813.28 issued under secs. 403, 61 Stat. 932; 7 U. S. C. Sup. 1153. Interprets or applies secs. 202, 204, 207, 208, 209, 210 and 212, 61 Stat. 924, 925, 927, 928, 929; 7 U. S. C. Sup. 1112, 1114, 1117, 1118, 1119, 1120, 1122.

§ 813.21 *Basic quotas for domestic areas.* There are hereby established, pursuant to subsection (a) of section 202 of the act, for domestic sugar producing areas for the calendar year 1951, the following quotas:

Area:	*Quotas in terms of short tons, raw value*
Domestic beet sugar	1,800,000
Mainland cane sugar	500,000
Hawaii	1,052,000
Puerto Rico	910,000
Virgin Islands	6,000

§ 813.22 *Basic quotas for other areas.* There are hereby established, pursuant to subsections (b) and (c) of section 202 of the act, for foreign countries for the calendar year 1951 the following quotas:

Area:	*Quotas in terms of short tons, raw value*
Republic of the Philippines	982,000
Cuba	2,712,600
Other foreign countries	37,400

§ 813.23 *Determination and proration of area deficits*—(a) *Deficit in quota for the Republic of the Philippines.* It is hereby determined pursuant to subsection (a) of section 204 of the act that for the calendar year 1951 the Republic of the Philippines will be unable by an amount of 200,000 short tons of sugar, raw value, to market the quota established for that area in § 813.22.

(b) *Proration of deficit in quota for the Republic of the Philippines.* An amount of sugar equal to the deficit determined in paragraph (a) of this section is hereby prorated, pursuant to subsection (a) of section 204 of the act, as follows:

Area:	*Additional quotas in terms of short tons, raw value*
Cuba	190,000
Foreign countries other than Cuba and the Republic of the Philippines	10,000

§ 813.24 *Proration of quota for foreign countries other than Cuba and the Republic of the Philippines*—(a) *Basic prorations.* The quota for foreign countries other than Cuba and the Republic of the Philippines is hereby prorated, pursuant to subsection (c) of section 202 of the act, among such countries as follows:

Country:	*Prorations in pounds raw value*
Belgium	442,154
Canada	847,633
China and Hongkong	432,848
Czechoslovakia	395,572
Dominican Republic	10,018,389
Dutch East Indies	317,573
Guatemala	503,140
Haiti	1,384,587
Honduras	5,156,918
Mexico	9,061,989
Netherlands	327,309
Nicaragua	15,355,523
Peru	16,697,266
Salvador	12,332,101
United Kingdom	526,824
Venezuela	435,684
Other countries	64,490
Subtotal	74,300,000
Unallotted reserve	500,000
Total	74,800,000

(b) *Additional prorations.* An amount of sugar equal to that part of the deficit prorated to foreign countries other than Cuba and the Republic of the Philippines under paragraph (b) of § 813.23 is hereby prorated, pursuant to subsection (d) of section 204 of the act, as follows:

Country:	*Additional prorations in pounds raw value*
Dominican Republic	5,391,705
Haiti	745,158
Mexico	4,876,989
Peru	8,986,148
Total	20,000,000

§ 813.25 *Direct-consumption portion of quotas or prorations*—(a) *Domestic areas.* Pursuant to subsections (a), (b), and (c) of section 207 of the act, the quotas established in § 813.21 for the following listed areas may be filled by direct-consumption sugar not in excess of the following amount for each such area:

Area:	*Direct-consumption sugar, short tons, raw value*
Hawaii	29,616
Puerto Rico	126,033
Virgin Islands	0

(b) *Other areas.* Pursuant to subsections (d) and (e) of section 207 of the act, the quotas established in §§ 813.22 and 813.23 for the following listed areas may be filled by direct-consumption sugar not in excess of the following amount for each such area:

Area:	*Direct-consumption sugar, short tons, raw value*
Republic of the Philippines	59,920
Cuba	375,000

(c) Pursuant to subsection (a) of section 204 of the act, only those prorations of the quota for foreign countries other than Cuba and the Republic of the Philippines established in paragraph (a) of § 813.24 may be filled by direct-consumption sugar.

§ 813.26 *Liquid sugar quotas.* There are hereby established, pursuant to section 208 of the act, for foreign countries for the calendar year 1951 quotas for liquid sugar as follows:

Country:	*Liquid sugar, wine gallons, 72 percent total sugar content*
Cuba	7,970,558
Dominican Republic	830,894
Other foreign countries	0

§ 813.27 *Restrictions on marketing and shipment.* Pursuant to section 209 of the act, all persons are hereby prohibited, during the calendar year 1951, from:

(a) Bringing or importing into the continental United States from the Territory of Hawaii, Puerto Rico, the Virgin Islands, or foreign countries, (1) any sugar or liquid sugar after the applicable quota, or the proration of any such quota, has been filled, or (2) any direct-consumption sugar after the direct-consumption portion of any such quota or proration thereof has been filled.

(b) Shipping, transporting, or marketing in interstate commerce, or in competition with sugar or liquid sugar shipped, transported, or marketed in interstate or foreign commerce, any sugar or liquid sugar produced from sugar beets or sugarcane grown in either the domestic beet sugar area or the mainland cane sugar area after the quota for such area has been filled.

§ 813.28 *Inapplicability of quota regulations.* Pursuant to section 212 of the act, §§ 813.21 to 813.27 shall not apply to (a) the first ten short tons, raw value, of sugar or liquid sugar imported from any foreign country, other than Cuba and the Republic of the Philippines, in the calendar year 1951; (b) the first ten short tons, raw value, of sugar or liquid sugar imported from any foreign country, other than Cuba and the Republic of the Philippines, in the calendar year 1951 for religious, sacramental, educational, or experimental purposes; (c) liquid sugar imported from any foreign country, other than Cuba and the Republic of the Philippines, in individual sealed containers not in excess of one and one-tenth gallons each; or (d) any sugar or liquid sugar imported, brought into, or produced or manufactured in the United States for the distillation of alcohol, or for livestock feed or for the production of livestock feed.

STATEMENT OF BASES AND CONSIDERATIONS

A. *Basic quotas.* The basic quotas established for domestic areas are in amounts specified in the act. Section 202 of the act provides that the quota for the Republic of the Philippines shall be 952,000 short tons "as specified in section 211 of the Philippine Trade Act of 1946." Quotas under the Sugar Act are established in terms of "short tons, raw value." An amount of 952,000 short tons of Philippine sugar of usual polarization is equivalent to 982,000 short tons of sugar, raw value. Similarly, the portion of this quota which may be imported as direct-consumption sugar, established as 56,000 short tons in subsection (d) of section 207 of the act, is equivalent to 59,920 short tons, raw value. The basic quotas for other foreign countries have been established by applying the statutory percentages to the difference between the consumption estimate and the sum of the quotas established for domestic areas and the Republic of the Philippines. The quota for foreign countries other than Cuba and the Republic of the Philippines has been prorated on the basis of the original proration made for 1937, as provided by the act. The amounts of the quotas and prorations which may be filled by direct-consumption sugar are as specified in the act. The liquid sugar quotas equal those specified in the act.

B. *Deficit in quota for the Republic of the Philippines.* Production of sugar in the Republic of the Philippines from the 1950–51 crop sugarcane is expected by the Government of the Philippines to total 1,062,000 short tons. If production reaches that level, the Philippines Government expects about 800,000 short tons to be shipped to the United States, but it recognizes the possibility of considerable error of estimate this early in the processing of the crop. The estimate of production for 1950–51 is 227,000 short tons over the estimate made a year earlier for the 1949–50 crop. Total shipments to the United States in 1950 were about 484,000 short tons, raw value. On the basis of the information now available a deficit of 200,000 short tons, raw value, is declared. This quantity is prorated to Cuba (95 percent) and other foreign countries (5 percent) as required by the act. This additional quota for foreign countries other than Cuba and the Republic of the Philippines has been prorated, in proportion to their basic quotas, to the four countries in this group which shipped raw sugar to the continental United States in 1949 and 1950. The quantity of sugar which may be entered from the Philippines under its statutory quota is not reduced by the declaration of a deficit.

After giving effect to the basic quotas and the proration of the Philippine deficit, the quotas in terms of short tons of sugar, raw value, for the several domestic sugar producing areas, the Republic of the Philippines, Cuba, and "Other foreign countries," are as follows:

BASIC QUOTAS, PRORATION OF PHILIPPINE DEFICIT AND ADJUSTED QUOTAS, 1951

[Short tons, raw value]

Production area	Basic quota	Proration of deficit in quota for Philippines	Adjusted quota
Domestic beet sugar	1,800,000	----------	1,800,000
Mainland cane sugar	500,000	----------	500,000
Hawaii [1]	1,052,000	----------	1,052,000
Puerto Rico [1]	910,000	----------	910,000
Virgin Islands	6,000	----------	6,000
Philippines [1]	[2] 982,000	(200,000)	782,000
Cuba [1]	2,712,600	190,000	2,902,600
Other foreign countries: [3]			
Belgium	221.1	----------	221.1
Canada	423.8	----------	423.8
China and Hongkong	216.4	----------	216.4
Czechoslovakia	197.8	----------	197.8
Dominican Republic	5,009.2	2,695.8	7,705.0
Dutch East Indies	158.9	----------	158.9
Guatemala	251.6	----------	251.6
Haiti	692.3	372.6	1,064.9
Honduras	2,578.5	----------	2,578.5
Mexico	4,531.0	2,438.5	6,969.5
Netherlands	163.6	----------	163.6
Nicaragua	7,677.8	----------	7,677.8
Peru	8,348.6	4,493.1	12,841.7
Salvador	6,166.0	----------	6,166.0
United Kingdom	263.4	----------	263.4
Venezuela	217.8	----------	217.8
Other countries	32.2	----------	32.2
Unallotted reserve	250.0	----------	250.0
Subtotal	37,400.0	10,000.0	47,400.0
Total	8,000,000	----------	8,000,000

[1] The following quantities may be entered as direct-consumption sugar: Hawaii, 29,616 tons; Puerto Rico, 126,033; Philippines, 59,920; Cuba, 375,000.

[2] Prorations of basic quota may be filled with direct-consumption or raw sugar. Prorations of Philippine deficit may be filled with raw sugar only.

[3] Regardless of deficit proration, by reason of section 204 (c) of the act the Republic of the Philippines retains its basic quota.

Done at Washington, D. C., this 27th day of December 1950.

Witness my hand and the seal of the Department of Agriculture.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12577; Filed, Dec. 29, 1950; 8:56 a. m.]

Chapter IX—Production and Marketing Administration (Marketing Agreements and Orders), Department of Agriculture

PART 903—MILK IN THE ST. LOUIS, MISSOURI, MARKETING AREA

ORDER AMENDING ORDER, AS AMENDED, REGULATING HANDLING

§ 903.0 *Findings and determinations.* The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and each of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and the applicable rules of practice and procedure, as amended, governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held at St. Louis, Missouri, on November 27–28, 1950, upon a proposed amendment to the tentative marketing agreement and to the order, as amended, regulating the handling of milk in the St. Louis, Missouri, marketing area. Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order, as amended, and as hereby further amended, and all of the terms and conditions of said order, as amended, and as hereby further amended, will tend to effectuate the declared policy of the act;

(2) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply of and demand for milk in the marketing area and the minimum prices specified in the order, as amended, and as hereby further amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(3) The said order, as amended, and as hereby further amended, regulates the handling of milk in the same manner as and is applicable only to persons in the respective classes of industrial and commercial activity specified in a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary, in the public interest, to make the amendment hereafter set forth effective not later than January 1, 1951, so as to reflect current marketing conditions. Any delay beyond January 1, 1951, in the effective date of this amendment to the order, as amended, will seriously threaten the supply of milk for the St. Louis, Missouri, marketing area. The provisions of the said amendment are well known to handlers—the public hearing having been held on November 27–28, 1950, and the decision having been executed by the Secretary on December 21, 1950. Therefore, reasonable time, under the circumstances, has been afforded persons affected to prepare for its effective date. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order, as amended, effective January 1, 1951, and that it would be impracticable, unnecessary, and contrary to the public interest to delay the effective date of this order for 30 days after its publication in the FEDERAL REGISTER (sec. 4 (c), Administrative Procedure Act, 60 Stat. 237, 5 U. S. C. 1001–1011).

(c) *Determinations.* It is hereby determined that handlers (excluding cooperative associations of producers who are not engaged in processing, distributing, or shipping milk covered by this order, amending the order, as amended, which is marketed within the St. Louis, Missouri, marketing area) or more than 50 percent of the milk which is marketed within the said marketing area, refused or failed to sign the proposed marketing agreement regulating the handling of milk in the said marketing area, and it is hereby further determined that:

(1) The refusal or failure of such handlers to sign said proposed marketing agreement tends to prevent the effectuation of the declared policy of the act;

(2) The issuance of this order amending the order, as amended, is the only practical means, pursuant to the declared policy of the act, of advancing the interests of producers of milk which is produced for sale in the said marketing area; and

(3) The issuance of this order amending the order, as amended, is approved or favored by at least two-thirds of the producers who, during the determined representative period (November 1950), were engaged in the production of milk for sale in the said marketing area.

Order relative to handling. It is therefore ordered, that on and after the effective date hereof, the handling of milk in the St. Louis, Missouri, marketing area, shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, and the aforesaid order, as amended, is hereby further amended as follows:

Amend § 903.5 (b) (1) by adding the following: "*Provided,* That for the delivery periods of January, February, and March 1951 the price for Class I milk shall be not less than the basic formula price plus $1.10 per hundredweight."

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup. 608c)

Issued at Washington, D. C., this 27th day of December 1950 to be effective on and after the 1st day of January 1951.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12523; Filed, Dec. 29, 1950; 8:53 a. m.]

PART 907—MILK IN MILWAUKEE, WIS., MARKETING AREA

ORDER AMENDING ORDER REGULATING HANDLING

Findings and determinations. The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in conection with the issuance of the aforesaid order, and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.) and the applicable rules of practice and procedure, as amended, governing the formulation of marketing agrements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order, regulating the handling of milk in the Milwaukee, Wisconsin, marketing area. Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds and other economic conditions which affect market supply and demand for milk in the said marketing area, and the minimum prices specified in the order, as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(3) The said order, as hereby amended, regulates the handling of milk in the same manner as and is applicable only to persons in the respective classes of industrial and commercial activity specified in a marketing agreement upon which a hearing has been held.

(d) *Additional findings.* It is necessary, in the public interest, to make effective not later than January 1, 1951, the present amendments to the said order, in order to reflect current marketing conditions. Any delay beyond January 1, 1951, in the effective date of this order as hereby amended, will present a serious threat to the supply of milk in this market in the year 1951. The provisions of the said order are well known to handlers—the public hearing having been held December 6–8, 1950, and the decision of the Secretary having been issued on December 21, 1950. Therefore, reasonable time, under the circumstances, has been afforded persons affected to prepare for its effective date. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order effective January 1, 1951, and that it would be impracticable, unnecessary, and contrary to the public interest to delay the effective date of this order 30 days after its publication in the FEDERAL REGISTER. (See section 4 (c) Administrative Procedure Act, Public Law 404, 79th Congress, 60 Stat. 237.)

(c) *Determinations.* It is hereby determined that handlers (excluding cooperative associations of producers who are not engaged in processing, distributing or shipping milk covered by this order amending the order, which is marketed within the Milwaukee, Wisconsin, marketing area) of more than 50 percent of the milk which is marketed within the said marketing area, refused or failed to sign the marketing agreement regulating the handling of milk in the said marketing area, and it is hereby further determined that:

(1) The refusal or failure of such handlers to sign said marketing agreement tends to prevent the effectuation of the declared policy of the act;

(2) The issuance of this order amending the order, is the only practical means, pursuant to the declared policy of the act, of advancing the interests of producers of milk which is produced for sale in the said marketing area; and

(3) The issuance of this order amending the order, is approved or favored by at least two-thirds of the producers who, during the determined representative period (November 1950), were engaged in the production of milk for sale in the said marketing area.

Order relative to handling. It is therefore ordered, that on and after the effective date hereof the handling of milk in the Milwaukee, Wisconsin, marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as hereby amended, and the aforesaid order, is hereby amended as follows:

1. Replace the period at the end of § 907.51 (a) with a colon and add the following proviso: "*Provided*, That the price for Class I milk during the months of January, February, and March 1951 shall be not less than $3.877."

2. Replace the period at the end of § 907.51 (b) with a colon and add the following proviso: "*Provided*, That the price for Class II milk during the months of January, February, and March 1951 shall be not less than $3.517."

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup. 608c)

Issued at Washington, D. C., this 27th day of December 1950, to be effective on and after the 1st day of January 1951.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12590; Filed, Dec. 29, 1950; 8:51 a. m.]

PART 941—MILK IN CHICAGO, ILL., MARKETING AREA

ORDER AMENDING ORDER, AS AMENDED, REGULATING HANDLING

Findings and determinations. The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of each of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended 7 U. S. C. 601 et seq.), and the applicable rules of practice and procedure, as amended, governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order, as amended, regulating the handling of milk in the Chicago, Illinois, marketing area. Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order, as amended, and as hereby further amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds and other economic conditions which affect market supply and demand for milk in the said marketing area, and the minimum prices specified in the order, as amended, and as hereby further amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(3) The said order, as amended, and as hereby further amended, regulates the handling of milk in the same manner as and is applicable only to persons in the respective classes of industrial and commercial activity specified in a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary, in the public interest, to make effective not later than January 1, 1951, the present amendments to the said order, as amended, in order to reflect current marketing conditions and to insure the production of an adequate supply of milk. Any delay beyond January 1, 1951, in the effective date of this order amending the order, as amended, will present a serious threat to the supply of milk for this marketing area in the year 1951. The provisions of the said order are well known to handlers, the public hearing having been held December 6–8, 1950, and the decision of the Secretary having been issued on December 21, 1950. Therefore, reasonable time, under the circumstances, has been afforded persons affected to

prepare for its effective date. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order, as amended, effective January 1, 1951, and that it would be impracticable, unnecessary, and contrary to the public interest to delay the effective date of this order 30 days after its publication in the FEDERAL REGISTER. (See section 4 (c) Administrative Procedure Act, Public Law 404, 79th Congress, 60 Stat. 237.)

(c) *Determinations.* It is hereby determined that handlers (excluding cooperative associations of producers who are not engaged in processing, distributing or shipping milk covered by this order amending the order, as amended, which is marketed within the Chicago, Illinois, marketing area) of more than 50 percent of the milk which is marketed within the said marketing area, refused or failed to sign the marketing agreement regulating the handling of milk in the said marketing area, and it is hereby further determined that:

(1) The refusal or failure of such handlers to sign said marketing agreement tends to prevent the effectuation of the declared policy of the act;

(2) The issuance of this order amending the order, as amended, is the only practical means, pursuant to the declared policy of the act, of advancing the interests of producers of milk which is produced for sale in the said marketing area; and

(3) The issuance of this order amending the order, as amended, is approved or favored by at least two-thirds of the producers who, during the determined representative period (November 1950), were engaged in the production of milk for sale in the said marketing area.

Order relative to handling. It is therefore ordered, That on and after the effective date hereof the handling of milk in the Chicago, Illinois, marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, and the aforesaid order, as amended, is hereby further amended as follows:

1. Replace the period at the end of § 941.5 (b) (1) with a colon and add the following proviso: "*Provided*, That the price for Class I milk during the delivery periods of January, February, and March 1951 shall be not less than $3.917."

2. Replace the period at the end of § 941.5 (b) (2) with a colon and add the following proviso: "*Provided*, That the price for Class II milk during the delivery periods of January, February, and March 1951 shall be not less than $3.517."

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup. 608c)

Issued at Washington, D. C. this 27th day of December 1950 to be effective on and after the 1st day of January 1951.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12586; Filed, Dec. 29, 1950; 8:50 a. m.]

[Lemon Reg. 362, Amdt. 1]

PART 953—LEMONS GROWN IN CALIFORNIA AND ARIZONA

LIMITATION OF SHIPMENTS

Findings. 1. Pursuant to the marketing agreement, as amended, and Order No. 53, as amended (7 CFR Part 953; 14 F. R. 3612), regulating the handling of lemons grown in the State of California or in the State of Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended, and upon the basis of the recommendation and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of the quantity of such lemons which may be handled, as hereinafter provided, will tend to effectuate the declared policy of the act.

2. It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice and engage in public rule-making procedure (60 Stat. 237; 5 U. S. C. 1001 et. seq.) because the time intervening between the date when information upon which this amendment is based became available and the time when this amendment must become effective in order to effectuate the declared policy of the Agricultural Marketing Agreement Act of 1937, as amended, is insufficient; and this amendment relieves restrictions on the handling of lemons grown in the State of California or in the State of Arizona.

Order, as amended. The provisions in paragraph (b) (1) (i) and (b) (1) (ii) of § 953.469 (Lemon Regulation 362, 15 F. R. 9221) are hereby amended to read as follows:

(i) District 1: 24 carloads;
(ii) District 2: 216 carloads.

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup., 608c)

Done at Washington, D. C., this 28th day of December 1950.

[SEAL] FLOYD F. HEDLUND,
Acting Director, Fruit and Vegetable Branch, Production and Marketing Administration.

[F. R. Doc. 50-12595; Filed, Dec. 29, 1950; 9:16 a. m.]

[Lemon Reg. 363]

PART 953—LEMONS GROWN IN CALIFORNIA AND ARIZONA

LIMITATION OF SHIPMENTS

§ 953.470 *Lemon Regulation 363*—(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 53, as amended (7 CFR Part 953; 14 F. R. 3612), regulating the handling of lemons grown in the State of California or in the State of Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and upon the basis of the recommendation and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of the quantity of such lemons which may be handled, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (60 Stat. 237; 5 U. S. C. 1001 et seq.) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. Shipments of lemons, grown in the State of California or in the State of Arizona, are currently subject to regulation pursuant to said amended marketing agreement and order; the recommendation and supporting information for regulation during the period specified herein was promptly submitted to the Department after an open meeting of the Lemon Administrative Committee on December 27, 1950, such meeting was held, after giving due notice thereof to consider recommendations for regulation, and interested persons were afforded an opportunity to submit their views at this meeting; the provisions of this section, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such lemons; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period hereinafter specified; and compliance with this section will not require any special preparation on the part of persons subject thereto which cannot be completed by the effective time thereof.

(b) *Order.* (1) The quantity of lemons grown in the State of California or in the State of Arizona which may be handled during the period beginning at 12:01 a. m., P. s. t., December 31, 1950, and ending at 12:01 a. m., P. s. t., January 7, 1951, is hereby fixed as follows:

(i) District 1: 25 carloads;
(ii) District 2: 200 carloads;
(iii) District 3: Unlimited movement.

(2) The prorate base of each handler who has made application therefor, as provided in the said amended marketing agreement and order, is hereby fixed in accordance with the prorate base schedule which is attached hereto and made a part hereof by this reference.

(3) As used in this section, "handled," "handler," "carloads," "prorate base," "District 1," "District 2" and "District

3," shall have the same meaning as when used in the said amended marketing agreement and order.

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup., 608c)

Done at Washington, D. C., this 28th day of December 1950.

[SEAL] FLOYD F. HEDLUND,
Acting Director, Fruit and Vegetable Branch, Production and Marketing Administration.

PRORATE BASE SCHEDULE

DISTRICT NO. 1

[Storage date: Dec. 24, 1950]

[12:01 a. m., Dec. 31, 1950, to 12:01 a. m., Jan. 14, 1951]

Handler	Prorate base (percent)
Total	100.000
Klink Citrus Association	27.514
Lemon Cove Association	23.399
Porterville Citrus Association, The	.383
The	.383
Tulare County Lemon & Grapefruit Association	44.326
California Citrus Groves, Inc., Ltd.	.274
Harding & Leggett	3.714
Sky Acres Ranch	.277
Zaninovich Bros., Inc.	.113
DISTRICT NO. 2	
Total	100.000
American Fruit Growers, Inc., Corona	.298
American Fruit Growers, Inc., Fullerton	.206
American Fruit Growers, Inc., Upland	.360
Eadington Fruit Co.	.031
Hazeltine Packing Co.	1.915
Ventura Coastal Lemon Co.	5.074
Ventura Pacific Co.	2.534
Glendora Lemon Growers Association	1.425
La Verne Lemon Association	.639
La Habra Citrus Association	.295
Yorba Linda Citrus Association	.165
Escondido Lemon Association	1.900
Alta Loma Heights Citrus Association	.764
Etiwanda Citrus Fruit Association	.611
Mountain View Fruit Association	.427
Old Baldy Citrus Association	1.125
San Dimas Lemon Association	.906
Upland Lemon Growers Association	5.134
Central Lemon Association	.126
Irvine Citrus Association	.107
Placentia Mutual Orange Association	.466
Corona Citrus Association	.535
Corona Foothill Lemon Co.	2.132
Jameson Co.	.789
Arlington Heights Citrus Co.	.664
College Heights Orange & Lemon Association	2.677
Chula Vista Citrus Association	.624
El Cajon Valley Citrus Association	.052
Escondido Cooperative Citrus Association	.223
Fallbrook Citrus Association	1.329
Lemon Grove Citrus Association	.201
Carpinteria Lemon Association	4.085
Carpinteria Mutual Citrus Association	4.602
Goleta Lemon Association	5.614
Johnston Fruit Co.	7.793
North Whittier Heights Citrus Association	.160
San Fernando Heights Lemon Association	4.561
Sierra Madre-Lamanda Citrus Association	1.649
Briggs Lemon Association	.955
Culbertson Lemon Association	2.066
Fillmore Lemon Association	.851
Oxnard Citrus Association	6.803
Rancho Sespe	.276
Santa Clara Lemon Association	3.270
Santa Paula Citrus Fruit Association	.994
Saticoy Lemon Association	4.701
Seaboard Lemon Association	4.579
Somis Lemon Association	2.984
Ventura Citrus Association	1.394
Ventura County Citrus Association	.012
Limoneira Co.	1.424
Teague-McKevett Association	.399
East Whittier Citrus Association	.113
Leffingwell Rancho Lemon Association	.136
Murphy Ranch Co.	.210
Chula Vista Mutual Lemon Association	.676
Index Mutual Association	.091
La Verne Cooperative Citrus Association	2.622
Orange Belt Fruit Distributors	.578
Ventura County Orange & Lemon Association	2.232
Whittier Mutual Orange & Lemon Association	.039
Evans Bros. Packing Co.	.005
Latimer, Harold	.015
San Antonio Orchard Co.	.017
Paramount Citrus Association, Inc.	.360

[F. R. Doc. 50-12594; Filed, Dec. 29, 1950; 9:15 a. m.]

[Orange Reg. 352]

PART 966—ORANGES GROWN IN CALIFORNIA OR IN ARIZONA

LIMITATION OF SHIPMENTS

§ 966.498 *Orange Regulation 352*—(a) *Findings.* (1) Pursuant to the provisions of Order No. 66, as amended (7 CFR Part 966; 14 F. R. 3614), regulating the handling of oranges grown in the State of California or in the State of Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and upon the basis of the recommendation and information submitted by the Orange Administrative Committee, established under the said amended order, and upon other available information, it is hereby found that the limitation of the quantity of such oranges which may be handled, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule making procedure, and postpone the effective date of this section until 30 days after publication thereof in the FEDERAL REGISTER (60 Stat. 237; 5 U. S. C. 1001 et seq.) because the time intervening between the date when information upon which this section is based became available and the time when this section must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. Shipments of oranges, grown in the State of California or in the State of Arizona, are currently subject to regulation pursuant to said amended order; the recommendation and supporting information for regulation during the period specified herein was promptly submitted to the Department after an open meeting of the Orange Administrative Committee on December 28, 1950, such meeting was held, after giving due notice thereof to consider recommendations for regulation, and interested persons were afforded an opportunity to submit their views at this meeting; the provisions of this section, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such oranges; it is necessary, in order to effectuate the declared policy of the act, to make this section effective during the period hereinafter specified; and compliance with this section will not require any special preparation on the part of persons subject thereto which cannot be completed by the effective time thereof.

(b) *Order.* (1) Subject to the size requirements in Orange Regulation 347 (7 CFR 966.493; 15 F. R. 8153), the quantity of oranges grown in the State of California or in the State of Arizona which may be handled during the period beginning at 12:01 a. m., P. s. t., December 31, 1950, and ending at 12:01 a. m., P. s. t., January 7, 1951, is hereby fixed as follows:

(i) *Valencia oranges.* (*a*) Prorate District No. 1: No movement;

(*b*) Prorate District No. 2: Unlimited movement;

(*c*) Prorate District No. 3: No movement;

(*d*) Prorate District No. 4: No movement.

(ii) *Oranges other than Valencia oranges.* (*a*) Prorate District No. 1: 700 carloads;

(*b*) Prorate District No. 2: 175 carloads;

(*c*) Prorate District No. 3: 65 carloads;

(*d*) Prorate District No. 4: Unlimited movement.

(2) The prorate base of each handler who has made application therefor, as provided in the said amended order, is hereby fixed in accordance with the prorate base schedule which is attached hereto and made a part hereof by this reference.

(3) As used in this section, "handled," "handler," "varieties," "carloads," and "prorate base" shall have the same meaning as when used in the said amended order; and the terms "Prorate District No. 1," "Prorate District No. 2," "Prorate District No. 3," and "Prorate District No. 4" shall each have the same meaning as given to the respective terms in § 966.107, as amended (15 F. R. 8712), of the current rules and regulations (7 CFR 966.103 et seq.), as amended (15 F. R. 8712).

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup. 608c)

Done at Washington, D. C., this 29th day of December 1950.

[SEAL] S. R. SMITH,
Director, Fruit and Vegetable Branch, Production and Marketing Administration.

PRORATE BASE SCHEDULE

[12:01 a. m. (P. s. t.) Dec. 31, 1950, to 12:01 a. m. (P. s. t.) Jan. 7, 1951]

ALL ORANGES OTHER THAN VALENCIA ORANGES

Prorate District No. 1

Handler	Prorate base (percent)
Total	100.0000
A. F. G. Lindsay	2.3724
A. F. G. Porterville	1.2918
Ivanhoe Cooperative Association	.6259
Sandilands Fruit Co	.2560
Doffiemyer & Son, W. Todd	.5249
Earlibest Orange Association	1.6958
Elderwood Citrus Association	.7991
Exeter Citrus Association	2.9903
Exeter Orange Growers Association	1.2154
Exeter Orchard Association	1.4231
Hillside Packing Association	1.2116
Ivanhoe Mutual Orange Association	1.0580
Klink Citrus Association	4.2344
Lemon Cove Association	2.1680
Lindsay Citrus Growers Association	2.6490
Lindsay Cooperative Citrus Association	1.1164
Lindsay Fruit Association	1.7414
Lindsay Orange Growers Association	1.3378
Naranjo Packing House	1.0620
Orange Cove Citrus Association	4.6339
Orange Packing Co	1.1991
Orosi Foothill Citrus Association	1.4799
Paloma Citrus Fruit Association	1.0060
Rocky Hill Citrus Association	1.3241
Sanger Citrus Association	4.4862
Sequoia Citrus Association	1.0265
Stark Packing Corp	2.8315
Visalia Citrus Association	1.9578
Waddell & Son	2.0762
Baird-Neece Corp	1.3950
Beattie Association, D. A	.7290
Grand View Heights Citrus Association	2.2113
Magnolia Citrus Association	1.7941
Porterville Citrus Association	1.3227
Richgrove Jasmine Citrus Association	1.5435
Strathmore Cooperative Association	1.3271
Strathmore District Orange Association	1.3668
Strathmore Fruit Growers Association	.8831
Strathmore Packing Association	1.6379
Sunflower Packing Association	1.9621
Sunland Packing House Co	2.3022
Terre Bella Citrus Association	1.6645
Tule River Citrus Association	1.1167
La Verne Cooperative Citrus Association	.2027
Lindsay Mutual Groves	1.2124
Martin Ranch	1.3784
Orange Cove Orange Growers	3.2304
Webb Packing Co., Inc	.3983
Woodlake Packing House	2.1088
Anderson Packing Co., R. M	1.0783
Andrews Bros. of Calif	.0000
Baker Bros	.3027
Barnes, J. L	.0253
Batkins Jr., Fred A	.0642
Bear State Packers, Inc	.2078
California Citrus Groves, Inc., Ltd	1.9388
Chess Co., Meyer W	.5007
Darby, Fred J	.0325
Darling, Curtis	.0014
Dubendorf, John	.1722
Edison Groves, Co	.0000

PRORATE BASE SCHEDULE—Continued

ALL ORANGES OTHER THAN VALENCIA ORANGES—continued

Prorate District No. 1—Continued

Handler	Prorate base (percent)
Evans Bros. Pkg. Co	0.0000
Harding & Leggett	2.3949
Hirasuna, Jimmie	.0058
Independent Growers, Inc	2.1961
Kim, Charles	.0497
Kroells Packing Co	2.2617
Larson, Kermit	.0289
Lo Bue Bros	1.8070
Maas, W. A	.0661
Marks, W. M	.3925
Minasian, Bob	.0025
Moore Packing Co., Myron	.0825
Nicholas, Richard	.0057
Randolph Marketing Co., Inc	1.9743
Reimers, Don H	.4041
Saba, Edward A	.0000
Shiba, Geo. G	.0014
Sky Acres Ranch	.0433
Swenson, L. W	.0465
Terry, Floyd	.0014
Toy, Chin	.0335
Woodlake Hts. Packing Corp	.4056
Wymer, E. C	.0000
Zanonovich Bros., Inc	1.8856

Prorate District No. 2

Total	100.0000
A. F. G. Alta Loma	.6395
A. F. G. Corona	.2185
A. F. G. Fullerton	.0343
A. F. G. Orange	.0331
A. F. G. Riverside	.9245
A. F. G. Santa Paula	.0431
Eadington Fruit Co., Inc	.7432
Hazeltine Packing Co	.1064
Krinard Packing Co	2.0141
Placentia Coop. Orange Association	.6456
Placentia Pioneer Valencia Growers Association	.0397
Signal Fruit Association	.8554
Azusa Citrus Association	1.3442
Covina Citrus Association	1.4922
Covina Orange Growers Association	.4950
Damerel-Allison Co	1.0780
Glendora Citrus Association	1.2826
Glendora Mutual Orange Association	.5547
Valencia Heights Orchard Association	.2044
Gold Buckle Association	2.7248
La Verne Orange Association	4.5407
Anaheim Valencia Orange Association	.0237
Fullerton Mutual Orange Association	.2782
La Habra Citrus Association	.1314
Orange County Valencia Association	.0126
Yorba Linda Citrus Association, The	.0216
Escondido Orange Association	.5348
Alta Loma Heights Citrus Association	.3856
Citrus Fruit Growers	.7072
Cucamonga Citrus Association	.0000
Etiwanda Citrus Association	.1984
Mountain View Fruit Association	.1296
Old Baldy Citrus Association	.4352
Rialto Heights Orange Growers	.3804
Upland Citrus Association	2.6440
Upland Heights Orange Association	1.1385
Consolidated Orange Growers	.0221
Frances Citrus Association	.0093
Garden Grove Citrus Association	.0250
Goldenwest Citrus Association, The	.1143
Oliver Heights Citrus Association	.0407
Santa Ana-Tustin Mutual Citrus Association	.0091
Santiago Orange Growers Association	.1248
Tustin Hills Citrus Association	.0247
Villa Park Orchard Association, The	.0328

PRORATE BASE SCHEDULE—Continued

ALL ORANGES OTHER THAN VALENCIA ORANGES—continued

Prorate District No. 2—Continued

Handler	Prorate base (percent)
Bradford Bros., Inc	0.2060
Placentia Mutual Orange Association	.2054
Placentia Orange Growers Association	.3107
Yorba Orange Growers Association	.0532
Call Ranch	.7036
Corona Citrus Association	.9733
Jameson Co	.4927
Orange Heights Orange Association	2.0661
Crafton Orange Growers Association	1.1777
East Highlands Citrus Association	.3850
Redlands Heights Groves	.5932
Redlands Orangedale Association	.8331
Rialto-Fontana Citrus Association	.3787
Break & Sons, Allen	.1646
Bryn Mawr Fruit Growers Association	.8465
Mission Citrus Association	1.1231
Redlands Cooperative Fruit Association	1.2587
Redlands Orange Growers Association	.9084
Redlands Select Groves	.5590
Rialto Orange Co	.3476
Southern Citrus Association	.9959
United Citrus Growers	.6955
Zilen Citrus Co	.5204
Arlington Heights Citrus Co	.9288
Brown Estate, L. V. W	1.8055
Gavilan Citrus Association	1.8776
Highgrove Fruit Association	.7280
McDermont Fruit Co	1.5335
Monte Vista Citrus Association	1.4712
National Orange Co	1.1250
Riverside Heights Orange Growers Association	1.2914
Sierra Vista Packing Association	.9277
Victoria Avenue Citrus Association	3.0905
Claremont Citrus Association	.9345
College Heights Orange & Lemon Association	2.1364
Indian Hill Citrus Association	1.1582
Pomona Fruit Growers Exchange	1.8911
Walnut Fruit Growers Association	.5560
West Ontario Citrus Association	1.1453
El Cajon Valley Citrus Association	.2645
Escondido Cooperative Citrus Association	.0444
San Dimas Orange Growers Association	1.1274
Canoga Citrus Association	.0652
North Whittier Heights Citrus Association	.1425
San Fernando Fruit Growers Association	.3162
San Fernando Heights Orange Association	.2811
Sierra Madre-Lamanda Citrus Association	.1617
Camarillo Citrus Association	.0107
Fillmore Citrus Association	1.1698
Ojai Orange Association	.8770
Piru Citrus Association	1.3000
Rancho Sespe	.0013
Santa Paula Orange Association	.1264
Ventura County Citrus Association	.0215
East Whittier Citrus Association	.0057
Murphy Ranch Co	.0742
Anaheim Cooperative Orange Association	.0629
Bryn Mawr Mutual Orange Association	.5132
Chula Vista Mutual Lemon Association	.1238
Euclid Avenue Orange Association	2.6262
Foothill Citrus Union, Inc	.6158
Garden Grove Orange Cooperative, Inc	.0349
Golden Orange Groves, Inc	.2768
Highland Mutual Groves, Inc	.2835
Index Mutual Association	.0097

PRORATE BASE SCHEDULE—Continued

ALL ORANGES OTHER THAN VALENCIA ORANGES—continued

Prorate District No. 2—Continued

Handler	Prorate base (percent)
La Verne Cooperative Citrus Association	3.2114
Mentone Heights Association	.6364
Orange Cooperative Citrus Association	.0520
Redlands Foothill Groves	2.0465
Redlands Mutual Orange Association	1.0270
Ventura County Orange & Lemon Association	.2697
Whittier Mutual Orange & Lemon Association	.0258
Allec Bros.	.0042
Babi-Juice Corp. of California	.3905
Banks, L. M.	.0231
Bennett Fruit Co., Inc.	.3404
Borden Fruit Co.	.0314
Cherokee Citrus Co., Inc.	.9776
Chess Co., Meyer W.	.4674
Dunning Ranch	.1562
Evans Bros. Packing Co.	1.4556
Gold Banner Association	1.8378
Granada Packing House	.9265
Hill Packing House, Fred A.	.9300
Knapp Packing Co., John C.	.5575
MacDonald Fruit Co.	.1125
Orange Belt Fruit Distributors	1.9016
Panno Fruit Co., Carlo	.0433
Paramount Citrus Association, Inc.	.3097
Placentia Orchard Co.	.0815
Prescott, John A.	.0075
Riverside Citrus Association	.2163
Ronald, P. W.	.0338
Summit Citrus Packers	.0453
Wall, E. T., Growers-Shipper	1.9894
Western Fruit Growers, Inc.	3.5200
Prorate District No. 3	
Total	100.0000
Allen & Allen Citrus Packing Co.	1.0957
Consolidated Citrus Growers	11.4458
McKellips Citrus Co., Inc.	5.5314
Phoenix Citrus Packing Co.	2.2418
Arizona Citrus Growers	14.3257
Chandler Heights Citrus Growers	4.1337
Desert Citrus Growers Co.	7.4269
Mesa Citrus Growers Association	25.7965
Tal'-Wi-Wi Ranches	.6239
Tempe Citrus Co.	1.6245
Yuma Mesa Fruit Growers Association	.3314
Leppla Henry Produce Co.	10.2512
Maricopa Citrus Co.	1.6413
Pioneer Fruit Co.	6.1003
Champion Produce Co., L. M.	.1369
Clark & Sons, J. H.	.3613
Commercial Citrus Packing Co.	1.0509
Hi Jolly Citrus Packing Co.	.6337
Ishikawa, Paul	.2464
Macchiaroli Fruit Co., James	.8954
Mattingly Fruit Co.	1.0150
Potato House, The	.4532
Saidy, H. A.	.0341
Sunny Valley Citrus Packing Co.	.3822
Valley Citrus Packing Co.	2.1658

[F. R. Doc. 50-12596; Filed, Dec. 29, 1950; 11:31 a. m.]

PART 967—MILK IN SOUTH BEND-LA PORTE, IND., MARKETING AREA

ORDER AMENDING ORDER, AS AMENDED, REGULATING HANDLING

Findings and determinations. The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of each of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and the applicable rules of practice and procedure, as amended, governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order, as amended, regulating the handling of milk in the South Bend-La Porte, Indiana, marketing area. Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order, as amended, and as hereby further amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds and other economic conditions which affect market supply and demand for milk in the said marketing area, and the minimum prices specified in the order, as amended, and as hereby further amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(3) The said order, as amended, and as hereby further amended, regulates the handling of milk in the same manner as and is applicable only to persons in the respective classes of industrial and commercial activity specified in a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary, in the public interest, to make effective not later than January 1, 1951, the present amendments to the said order, as amended, in order to reflect current marketing conditions and to insure the production of an adequate supply of milk. Any delay beyond January 1, 1951, in the effective date of this order amending the order, as amended, will present a serious threat to the supply of milk for this marketing area in the year 1951. The provisions of the said order are well known to handlers, the public hearing having been held December 6-8, 1950, and the decision of the Secretary having been issued on December 21, 1950. Therefore, reasonable time, under the circumstances, has been afforded persons affected to prepare for its effective date. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order, as amended, effective January 1, 1951, and that it would be impracticable, unnecessary, and contrary to the public interest to delay the effective date of this order 30 days after its publication in the FEDERAL REGISTER. (See section 4 (c) Administrative Procedure Act, Public Law 404, 79th Congress, 60 Stat. 237.)

(c) *Determinations.* It is hereby determined that handlers (excluding cooperative associations of producers who are not engaged in processing, distributing or shipping milk covered by this order amending the order, as amended, which is marketed within the South Bend-La Porte, Indiana, marketing area) of more than 50 percent of the milk which is marketed within the said marketing area, refused or failed to sign the marketing agreement regulating the handling of milk in the said marketing area, and it is hereby further determined that:

(1) The refusal or failure of such handlers to sign said marketing agreement tends to prevent the effectuation of the declared policy of the act;

(2) The issuance of this order amending the order, as amended, is the only practical means, pursuant to the declared policy of the act, of advancing the interests of producers of milk which is produced for sale in the said marketing area; and

(3) The issuance of this order amending the order, as amended, is approved or favored by at least two-thirds of the producers who, during the determined representative period (November 1950), were engaged in the production of milk for sale in the said marketing area.

Order relative to handling. It is therefore ordered, that on and after the effective date hereof the handling of milk in the South Bend-La Porte, Indiana, marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, and the aforesaid order, as amended, is hereby further amended as follows:

1. Replace the period at the end of § 967.51 with a colon and add the following proviso to such section: "*Provided further*, That the prices per hundredweight for skim milk and butterfat in Class I and Class II milk during the delivery periods of January, February and March 1951 shall be not less than $1.218 and $78.34, respectively."

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup. 608c)

Issued at Washington, D. C., this 27th day of December, 1950, to be effective on and after the 1st day of January 1950.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12589; Filed, Dec. 29, 1950; 8:50 a. m.]

PART 969—MILK IN SUBURBAN CHICAGO, ILL., MARKETING AREA

ORDER AMENDING ORDER, AS AMENDED, REGULATING HANDLING

Findings and determinations. The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of each of the previously issued amend-

ments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and the applicable rules of practice and procedure, as amended, governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order, as amended, regulating the handling of milk in the Suburban Chicago, Illinois, marketing area. Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order, as amended, and as hereby further amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds and other economic conditions which affect market supply and demand for milk in the said marketing area, and the minimum prices specified in the order, as amended, and as hereby further amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(3) The said order, as amended, and as hereby further amended, regulates the handling of milk in the same manner as and is applicable only to persons in the respective classes of industrial and commercial activity specified in a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary, in the public interest, to make effective not later than January 1, 1951, the present amendments to the said order, as amended, in order to reflect current marketing conditions and to insure the production of an adequate supply of milk. Any delay beyond January 1, 1951, in the effective date of this order amending the order, as amended, will present a serious threat to the supply of milk for this marketing area in the year 1951. The provisions of the said order are well known to handlers, the public hearing having been held December 6–8, 1950, and the decision of the Secretary having been issued on December 21, 1950. Therefore, reasonable time, under the circumstances, has been afforded persons affected to prepare for its effective date. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order, as amended, effective January 1, 1951, and that it would be impracticable, unnecessary, and contrary to the public interest to delay the effective date of this order 30 days after its publication in the FEDERAL REGISTER. (See section 4 (c) Administrative Procedure Act, Public Law 404, 79th Congress, 60 Stat. 237.)

(c) *Determinations.* It is hereby determined that handlers (excluding cooperative associations of producers who are not engaged in processing, distributing or shipping milk covered by this order amending the order, as amended, which is marketed within the Suburban Chicago, Illinois, marketing area) of more than 50 percent of the milk which is marketed within the said marketing area, refused or failed to sign the marketing agreement regulating the handling of milk in the said marketing area, and it is hereby further determined that:

(1) The refusal or failure of such handlers to sign said marketing agreement tends to prevent the effectuation of the declared policy of the act;

(2) The issuance of this order amending the order, as amended, is the only practical means, pursuant to the declared policy of the act, of advancing the interests of producers of milk which is produced for sale in the said marketing area; and

(3) The issuance of this order amending the order, as amended, is approved or favored by at least two-thirds of the producers who, during the determined representative period (November 1950), were engaged in the production of milk for sale in the said marketing area.

Order relative to handling. It is therefore ordered, that on and after the effective date hereof the handling of milk in the Suburban Chicago, Illinois, marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, and the aforesaid order, as amended, is hereby further amended as follows:

1. Replace the period at the end of § 969.5 (b) (1) with a colon and add the following proviso: "*Provided*, That the prices for Grade A and Grade B Class I milk during the delivery periods of January, February and March 1951 shall be not less than $3.917 and $3.817, respectively."

2. Replace the period at the end of § 969.5 (b) (2) with a colon and add the following proviso: "*Provided*, That the prices for Grade A and Grade B Class II milk during the delivery periods of January, February and March 1951 shall be not less than $3.517 and $3.417, respectively."

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup. 608c)

Issued at Washington, D. C., this 27th day of December 1950, to be effective on and after the 1st day of January 1951.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50–12587; Filed, Dec. 29, 1950; 8:50 a. m.]

PART 991—MILK IN ROCKFORD-FREEPORT, ILL., MARKETING AREA

ORDER AMENDING ORDER, AS AMENDED, REGULATING HANDLING

Findings and determinations. The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the aforesaid order and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and the applicable rules of practice and procedure, as amended, governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order, as amended, regulating the handling of milk in the Rockford-Freeport, Illinois, marketing area. Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order, as amended, and as hereby further amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds and other economic conditions which affect market supply and demand for milk in the said marketing area and the minimum prices specified in the order, as amended, and as hereby further amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(3) The said order, as amended, and as hereby further amended, regulates the handling of milk in the same manner as and is applicable only to persons in the respective classes of industrial and commercial activity specified in a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary, in the public interest, to make effective not later than January 1, 1951, the present amendments to the said order, as amended, in order to reflect current marketing conditions and to insure the production of an adequate supply of milk. Any delay beyond January 1, 1951, in the effective date of this order, amending the order, as amended, will present a serious threat to the supply of milk for this marketing area in the year 1951. The provisions of the said order are well known to handlers, the public hearing having been held December 6–8, 1950, and the decision of the Secretary having been issued on Decem-

ber 21, 1950. Therefore, reasonable time, under the circumstances, has been afforded persons affected to prepare for its effective date. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order, as amended, effective January 1, 1951, and that it would be impracticable, unnecessary, and contrary to the public interest to delay the effective date of this order 30 days after its publication in the FEDERAL REGISTER. (See section 4 (c), Administrative Procedure Act, Public Law 404, 79th Congress, 60 Stat. 237.)

(c) *Determination.* It is hereby determined that handlers (excluding cooperative associations of producers who are not engaged in processing, distributing or shipping milk covered by this order amending the order, as amended, which is marketed within the Rockford-Freeport, Illinois, marketing area) of more than 50 percent of the milk which is marketed within the said marketing area, refused or failed to sign the marketing agreement regulating the handling of milk in the said marketing area, and it is hereby further determined that:

(1) The refusal or failure of such handlers to sign said marketing agreement tends to prevent the effectuation of the declared policy of the act;

(2) The issuance of this order amending the order, as amended, is the only practical means, pursuant to the declared policy of the act, of advancing the interests of producers of milk which is produced for sale in the said marketing area; and

(3) The issuance of this order amending the order, as amended, is approved or favored by at least two-thirds of the producers who, during the determined representative period (November 1950), were engaged in the production of milk for sale in the said marketing area.

Order relative to handling. It is therefore ordered, that on and after the effective date hereof the handling of milk in the Rockford-Freeport, Illinois, marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, and the aforesaid order, as amended, is hereby further amended as follows:

1. Add to § 991.51 the following proviso: "*Provided*, That the price for Grade "A" and Nongrade "A" Class I milk during the delivery periods of January, February, and March 1951 shall be not less than $3.917 and $3.817, respectively."

2. Add to § 991.52 the following proviso: "*Provided*, That the price for Grade "A" and Nongrade "A" Class II milk during the delivery periods of January, February, and March 1951 shall be not less than $3.517 and $3.417, respectively."

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. and Sup. 608c)

Issued at Washington, D. C., this 27th day of December 1950, to be effective on and after the 1st day of January 1951.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12588; Filed, Dec. 29, 1950; 8:50 a. m.]

TITLE 9—ANIMALS AND ANIMAL PRODUCTS

Chapter I—Bureau of Animal Industry, Department of Agriculture

Subchapter A—Meat Inspection Regulations

PART 27—IMPORTED PRODUCTS

COUNTRIES FROM WHICH PRODUCT (MEAT, MEAT BYPRODUCT, AND MEAT FOOD PRODUCT) IS ELIGIBLE FOR IMPORTATION INTO THE UNITED STATES

Pursuant to the authority vested in the Secretary of Agriculture by section 306 of the Tariff Act of June 17, 1930 (19 U. S. C. 1306), and after public notice (15 F. R. 8589) and due consideration of all relevant material presented pursuant thereto, § 27.2 (b) of the regulations in 9 CFR, Chapter I, Subchapter A, as amended, issued under said section, is hereby amended to read as follows, for the purpose of adding Mexico to the list of countries specified therein from which meat, meat byproduct, and meat food product may be imported into the United States as provided in said regulations:

(b) It has been determined by the Secretary of Agriculture that product from the following foreign countries, covered by foreign meat inspection certificates of the country of origin as required by § 27.6, except fresh, chilled, or frozen or other prohibited or restricted product from countries in which the contagious and communicable disease of rinderpest or of foot-and-mouth disease exists as listed in Part 94 of this chapter, as amended, is eligible for importation into the United States after inspection and marking as required by this subchapter:

Argentina.	Luxembourg.
Australia.	Madagascar.
Belgium.	Mexico.
Brazil.	Netherlands.
Canada.	New Zealand.
Cuba.	Northern Ireland.
Czechoslovakia.	Norway.
Denmark.	Paraguay.
Dominican Republic.	Poland.
England and Wales.	Scotland.
Finland.	Spain.
France.	Sweden.
Iceland.	Switzerland.
Ireland (Eire).	Uruguay.
Italy.	Venezuela.

Effective date: The foregoing amendment shall be effective on December 30, 1950.

Since the amendment relieves restrictions it may properly be made effective under section 4 (c) of the Administrative Procedure Act (5 U. S. C. 1003 (c)) less than 30 days after its publication in the FEDERAL REGISTER.

(Sec. 306, 46 Stat. 689; 19 U. S. C. 1306)

Done at Washington, D. C., this 27th day of December 1950. Witness my hand and the seal of the United States Department of Agriculture.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12406; Filed, Dec. 29, 1950; 8:45 a. m.]

TITLE 13—BUSINESS CREDIT

Chapter I—Reconstruction Finance Corporation

PART 50—FEDERAL NATIONAL MORTGAGE ASSOCIATION

CROSS REFERENCE: Part 50 is superseded by Title 24, Chapter IV, Part 400, *infra*.

TITLE 14—CIVIL AVIATION

Chapter I—Civil Aeronautics Board

[Regs., Serial No. SR-358]

PART 1—AIRWORTHINESS CERTIFICATES

PART 3—AIRPLANE AIRWORTHINESS; NORMAL, UTILITY, ACROBATIC, AND RESTRICTED-PURPOSE CATEGORIES

PART 4a—AIRPLANE AIRWORTHINESS

PART 4b—AIRPLANE AIRWORTHINESS; TRANSPORT CATEGORIES

PART 6—ROTORCRAFT AIRWORTHINESS

PART 13—AIRCRAFT ENGINE AIRWORTHINESS

PART 14—AIRCRAFT PROPELLER AIRWORTHINESS

PART 15—AIRCRAFT EQUIPMENT AIRWORTHINESS

EXTENSION OF DATE FOR COMPLIANCE WITH IDENTIFICATION PLATE REQUIREMENTS

Adopted by the Civil Aeronautics Board at its office in Washington, D. C., on the 27th day of December 1950.

Amendments 2-1, 3-1, 4a-3, 4b-1, 6-3, 13-1, 14-1, and 15-1, adopted November 2, 1949, established new requirements for identification plates for type certificated aircraft, aircraft engines, propellers, and applicances. As adopted, these requirements were to be effective December 7, 1949. Upon being advised that certain manufacturers would not be able to obtain the new plates on time to meet the established effective date, in Special Civil Air Regulation SR-339, adopted December 6, 1949, the Board extended the date for compliance to March 7, 1950. On March 3, 1950, the Board adopted Special Civil Air Regulation SR-342, which authorized manufacturers who had stocks of plates on hand on December 6, 1949, to use such stock up to, but no later than, December 31, 1950. The basis for our action at that time was the undue economic burden which would result from requiring the manufacturers to discard their entire stock of old plates in view of the fact that the new requirements for identification plates were based on a long range rather than an immediate or direct contribution to air safety.

We are now faced with a new appeal for permission to use present stocks of identification plates which at least in one case is claimed to be a two-year supply. Upon this record alone we would not be inclined to grant any further extension of the compliance date. However, the current demands upon our domestic economy resulting in shortages of basic metals make it imperative that every

effort be taken to utilize all material on hand. In this case air safety will not be jeopardized with the use of non-fireproof identification plates, and we therefore consider it advisable to extend the date of compliance until December 31, 1952.

For the reasons set forth above, notice and public procedure hereon are impractical and contrary to the interest of the public, and the Board finds that good cause exists for making this regulation effective on less than 30 days' notice.

In consideration of the foregoing the Civil Aeronautics Board hereby makes and promulgates a Special Civil Air Regulation effective January 1, 1951, to read as follows:

Contrary provisions of the Civil Air Regulations notwithstanding, the identification plate requirements adopted by the Board on November 2, 1949, shall be applicable with respect to aircraft and aircraft components manufactured on and after April 7, 1950: *Provided*, That manufacturers who on December 6, 1949, had on hand a supply of identification plates which met the requirements of the then effective Civil Air Regulations may use such identification plates until such supply is exhausted or until December 31, 1952, whichever date is earlier.

This regulation supersedes Special Civil Air Regulation Serial Number SR–342, and shall terminate December 31, 1952, unless sooner superseded or rescinded.

(Sec. 205, 52 Stat. 984; 49 U. S. C. 425. Interpret or apply secs. 601, 603, 52 Stat. 1007, 1008; 49 U. S. C. 551, 553)

By the Civil Aeronautics Board.

[SEAL] FRED A. TOOMBS, *Acting Secretary.*

[F. R. Doc. 50–12575; Filed, Dec. 29, 1950; 9:00 a. m.]

[Supp. 2]

PART 18—MAINTENANCE, REPAIR, AND ALTERATION OF CERTIFICATED AIRCRAFT, ENGINES, PROPELLERS, AND INSTRUMENTS

PROCEDURE FOR OBTAINING APPROVAL OF MAJOR REPAIRS AND ALTERATIONS PERFORMED ON U. S. CIVIL AIRCRAFT IN CANADA

Proposed rules regarding compliance with § 18.11–1 were published on October 7, 1950, at 15 F. R. 6789. Interested persons were given an opportunity to submit data, views, or arguments. Consideration has been given to all relevant matters presented. The following rules are hereby adopted:

§ 18.11–1 *Procedure for approval of major repairs and alterations performed on U. S. civil aircraft in Canada (CAA rules which apply to § 18.11).* (a) In order to expedite the return to service in Canada of a U. S. civil aircraft which has undergone a major repair and/or alteration, such repairs and/or alterations may be approved by an aircraft inspector of the Canadian Department of Transport, Air Services Branch, as a duly authorized representative for the Administrator, provided that:

(1) The major repair and/or alteration does not affect the CAA approved aircraft operating limitations, and

(2) The major repair and/or alteration has been accomplished by or under the direct supervision of a holder of a currently effective U. S. mechanic's certificate, and

(3) The Repair and Alteration Form (Form ACA–337) and log book entries have been completed by the mechanic in accordance with § 18.16 and the appropriate parts of the Administrator's policies and interpretations in Part 18, and

(4) The repairs and/or alterations have been found airworthy in accordance with U. S. requirements by the Canadian aircraft inspector, and

(5) The inspection report furnished the aircraft owner by the Canadian aircraft inspector is retained with the copies of the Repair and Alteration Form (Form ACA–337) and presented to a CAA agent or representative immediately upon return of the aircraft to the United States.

(b) Approval by an aircraft inspector of the Canadian Department of Transport shall not be required where the repairs and/or alterations are accomplished by a Canadian repair station having a Repair Station Certificate and appropriate ratings issued by the Administrator.

(Sec. 205, 52 Stat. 984; 49 U. S. C. 425. Interprets or applies secs. 601, 605, 52 Stat. 1007, 1010, as amended; 49 U. S. C. 551, 555.)

These rules shall become effective on February 1, 1951.

[SEAL] DONALD W. NYROP, *Administrator of Civil Aeronautics.*

[F. R. Doc. 50–12585; Filed, Dec. 29, 1950; 8:50 a. m.]

[Supp. 7, Amdt. 59]

PART 60—AIR TRAFFIC RULES

DANGER AREA ALTERATIONS

The danger area alterations appearing hereinafter have been coordinated with the civil operators involved, the Army, the Navy, and the Air Force, through the Air Coordinating Committee, Airspace Subcommittee, and are adopted when indicated in order to promote safety of the flying public. Compliance with the notice, procedures, and effective date provisions of section 4 of the Administrative Procedure Act would be impracticable and contrary to the public interest, and therefore is not required. Title 14, § 60.13–1 is amended as follows:

1. The Barstow, California, area, published on August 17, 1949, in 14 F. R. 5122, is amended by changing the "Description by Geographical Coordinates" column to read: "Beginning at lat. 35°37'45" N, long. 116°29'40" W; due S to lat. 35°34'30" N; due E to long. 116°23'30" W; SE to lat. 35°27'55" N, long. 116°18'45" W; due S to lat. 35°18'45" N; SW along Amber Airway No. 2 to lat. 35°07'00" N, long. 116°34'00" W; W to lat. 35°07'20" N, long. 116°43'00" W; due N to lat. 35°08'00" N; due W to long. 116°45'00" W; due N to lat. 35°09'00" N; due W to long. 116°47'00" W; due S to lat. 35°08'00" N; due W to long. 116°48'00" W; due N to lat. 35°10'00" N; due W to long. 116°49'00" W; due N to lat. 35°19'00" N; due W to long. 116°55'20" W; due N to lat. 35°37'45" N; due E to lat. 35°37'45" N, long. 116°29'40" W, point of beginning.

2. The Fallon, Nevada, area, published on April 21, 1949, in 14 F. R. 1913, and revised on May 12, 1950, in 15 F. R. 2839, is further revised by adding the following:

Name and location (chart)	Description by geographical coordinates	Designated altitudes	Time of designation	Using agency
Fallon (Reno chart).	(4) Eastgate Target: A circular area having a radius of 5 miles centered at lat. 39°15'00" N, long. 118°15'00" W, excluding that portion lying within Red Airway No. 15.	Surface to 15,000 feet.	Continuous (firing will be conducted only when ceiling and visibility in vicinity of danger area are at least 1,500 feet and 3 miles).	12th Naval District, San Diego, Calif.

(Sec. 205, 52 Stat. 984, as amended; 49 U. S. C. 425. Interprets or applies sec. 601, 52 Stat. 1007, as amended; 49 U. S. C. 551)

This amendment shall become effective on January 5, 1951.

[SEAL] DONALD W. NYROP, *Administrator of Civil Aeronautics.*

[F. R. Doc. 50–12473; Filed, Dec. 29, 1950; 8:46 a. m.]

Chapter II—Civil Aeronautics Administration, Department of Commerce

PART 405—GENERAL PROCEDURES

Under section 205 of the Civil Aeronautics Act of 1938, as amended, the Administrator of Civil Aeronautics is empowered to make and amend such general or special procedures, pursuant to and consistent with the provisions of the act, as he deems necessary to carry out such provisions and to exercise and perform his powers and duties under the act.

Acting pursuant to the foregoing authority, and in accordance with section 3 of the Administrative Procedure Act, I hereby revise Part 405 of this chapter to read:

SUBPART A—INTRODUCTION

SUBPART B—FORMAL AND INFORMAL PROCEDURES

AUTHORITY: §§ 405.1 to 405.15 issued under sec. 205, 52 Stat. 984, as amended; 49 U. S. C. 425.

SUBPART A—INTRODUCTION

§ 405.1 *Definitions of terms.* As used in this part:

(a) "Acts" shall mean Civil Aeronautics Act of 1938, as amended.

(b) "Administration" shall mean Civil Aeronautics Administration.

(c) "Administrator" shall mean Administrator of Civil Aeronautics.

(d) "Board" shall mean Civil Aeronautics Board.

§ 405.2 *Civil aeronautics procedures.* The act provides that certain civil aeronautics functions shall be performed by the Administration, while others shall be performed by the Board. Accordingly, persons desiring information with respect to civil aeronautics procedures should examine not only this chapter but also Chapter I of this title.

SUBPART B—FORMAL AND INFORMAL PROCEDURES

§ 405.11 *Public information.* Except to the extent that there is involved any function of the United States requiring secrecy in the public interest, or any matter relating solely to the internal management of the Administration:

(a) The Administration will separately state and currently publish in the FEDERAL REGISTER:

(1) Descriptions of its central and field organization, including delegations by the Administrator of final authority and the established places at which, and methods by which, the public may secure information or make submittals or requests. Organization of the Administration will be promulgated uncodified in the "Notices" section of the FEDERAL REGISTER, and in summarized form in the United States Government Organization Manual. In addition, it will be available as Part 400, Regulations of the Administrator, from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C. Amendments to Part 400 will be obtainable without charge, from the Aviation Information Office, Civil Aeronautics Administration, Washington 25, D. C. All current parts and amendments to the Regulations of the Administrator will be listed in the Civil Aeronautics Journal, published monthly by the Administration and available from the Superintendent of Documents.

(2) Statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available as well as forms and instructions as to the scope and contents of all papers, reports, or examinations. Procedures of the Administration will be promulgated in Parts 405 through 419 of this chapter. In addition, they will be available as Parts 405 through 419, Regulations of the Administrator, from the Superintended of Documents, Government Printing Office. Amendments to Parts 405 through 419 will be obtainable without charge, from the Aviation Information Office of the Administration.

(3) Substantive rules adopted by the Administration as authorized by law, and statements of general policy or interpretations formulated and adopted by the Administration for the guidance of the public, but not rules addressed to, and served upon, named persons in accordance with law. Rules, policies, and interpretations of the Administration issued primarily pursuant to statutes conferring authority on the Administrator will be promulgated in Parts 420 through 699 of this chapter. In addition, they will be available as Parts 420 through 699, Regulations of the Administrator, from the Superintendent of Documents, Government Printing Office. Amendments to Parts 420 through 699 will be obtainable without charge, from the Aviation Information Office of the Administration. Rules, policies, and interpretations of the Administration issued primarily pursuant to Civil Air Regulations delegating authority to the Administrator, will be promulgated in Parts 1 through 99 and 420 through 699 of this title. In addition, many of these rules, etc., will be found in the following publications:

(i) Civil Aeronautics Manuals will correspond with those individual parts in Subchapter A of Chapter I which have been supplemented by the Administration. These Manuals will be available from the Superintendent of Documents, Government Printing Office, and supplements to these Manuals will be obtainable without charge from the Aviation Information Office of the Administration. All current Manuals and supplements will be listed in the Civil Aeronautics Journal.

(ii) Flight Information Manual, issued semi-annually, and Airman's Guide, issued bi-weekly, which supplements the Manual, will include rules, etc., which are of value to persons operating aircraft. They will be available from the Superintendent of Documents, Government Printing Office.

(iii) Technical Standard Orders will consist of technical standards dealing with aircraft, airports, airmen, and airways. They will be obtainable without charge, from the Aviation Information Office of the Administration.

(iv) Airworthiness Directives will consist of technical standards dealing with airworthiness of aircraft. They will be obtainable without charge, from the Aviation Information Office of the Administration.

(b) The Administration will publish or, in accordance with published rules, make available for public inspection, all final opinions or orders in the adjudication of cases (except those required for good cause to be held confidential and not cited as precedents) and all rules.

(c) Save as otherwise required by statute, the Administration will, in accordance with published rules, make available to persons properly and directly concerned, all matters of official record except information held confidential for good cause found.

§ 405.12 *Drafting of rules, etc.* The Administrator's rules, policies, and interpretations result from recommendations made by the industry or from research and experimentation conducted by technical offices of the Administration. Such rules, etc., will be prepared by the technical offices assigned responsibility for the subject matter in the organization of the Civil Aeronautics Administration, and thereafter will be submitted through the General Counsel's office to the Administrator for final adoption and promulgation. Before the Administrator adopts rules, the Administration may issue a draft of the proposed rules to the industry, requesting its views and comments, and will comply with § 405.13.

§ 405.13 *Making of rules.* Except to the extent that there is involved any military, naval, or foreign affairs function of the United States, or any matter relating to Administration management or personnel or to public property, loans, grants, benefits, or contracts:

(a) The Administration will publish general notice of proposed rule making in the FEDERAL REGISTER (unless all persons subject to the rules are named and either are personally served or otherwise have actual notice of the rules in accordance with law). The notice will include a statement of the time, place, and nature of the public rule making proceedings; a reference to the authority under which the rules are proposed; and either the terms or the substance of the proposed rules or a description of the subjects and issues involved. Except where notice is required by statute, this subsection will not apply to interpretative rules, general statements of policy, rules of Administration organization, procedure, or practice, or in any situation in which the Administrator for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice thereon is impracticable, unnecessary, or contrary to the public interest.

(b) After complying with the notice requirements of this section, the Administration will afford interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity to present the same orally in any manner; and, after consideration of all relevant matter presented, the Administration will incorporate in any rules adopted, a concise general statement of their basis and purpose. Except where hearing is required by statute, this subsection will not apply to interpretative rules, general statements of policy, rules of Administration organization, procedure, or practice, or in any situation in which the Administration for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that public procedures thereon are impracticable, unnecessary, or contrary to the public interest. Where rules are required by statute to be made on the record after opportunity for an Administration hearing, the requirements of sections 7 and 8 of the Administrative Procedure Act will apply in place of the provisions of this paragraph.

(c) The publication or service by the Administration of any substantive rules (other than those granting or recognizing exemptions or relieving restrictions,

or interpretative rules and statements of policy) will be made not less than 30 days prior to the effective date of the rules, except as otherwise provided by the Administration upon good cause found and published with the rules.

(d) Any interested person may petition for the issuance, amendment, or repeal of Administration rules. Such petition shall be addressed to the Civil Aeronautics Administration, Washington 25, D. C. It shall set forth clearly and concisely the petitioner's interest in the subject matter, the specific action desired, the facts requiring or justifying the action, and the purpose that would be served by granting the action.

§ 405.14 *Requests for informal appearances.* Any interested person may request and will be granted an opportunity to appear informally before the proper official or officials of the Administration for the presentation, adjustment, or determination of an issue or controversy pertaining to a function of the Administration. A request for such an appearance shall be submitted in writing and addressed to the Civil Aeronautics Administration, Washington 25, D. C., or to its nearest Regional or District Office.

§ 405.15 *Availability of rules, etc.* Inquiries regarding the availability of copies of current organization, procedures, rules, policies, or interpretations issued by the Administration shall be addressed to its Aviation Information Office, Washington 25, D. C.

This part shall become effective upon publication in the FEDERAL REGISTER.

[SEAL] DONALD W. NYROP,
Administrator of Civil Aeronautics.

[F. R. Doc. 50-12474; Filed, Dec. 29, 1950; 8:46 a. m.]

PART 406—CERTIFICATION PROCEDURES

Under sections 205, 309, 602–609, 901, and 1001–1009 of the Civil Aeronautics Act of 1938, as amended, the Administrator of Civil Aeronautics is empowered (1) to provide for the examination and re-examination of airmen, aircraft, aircraft engines, propellers, appliances, air carriers, air navigation facilities, and air agencies, (2) to issue, administer, and enforce the provisions of, airman certificates, type certificates, production certificates, airworthiness certificates, air carrier operating certificates, air navigation facility certificates, and air agency certificates, and to alter, amend, and modify such certificates after investigation and upon notice and hearing, and (3) to make and amend such general or special procedures as he deems necessary to exercise and perform such powers and duties.

Acting pursuant to the foregoing authority, and in accordance with section 3 of the Administrative Procedure Act, I hereby revise Part 406 of this chapter to read:

SUBPART A—INTRODUCTION

Sec.
406.1 Definitions of terms.
406.2 Use of forms, etc.

SUBPART B—ISSUANCE OF CERTIFICATES

Sec.
406.11 General.
406.12 Medical certificates.
406.13 Airman certificates.
406.14 Aircraft certificates.
406.15 Air carrier certificates.
406.16 Air agency certificates.
406.17 Air navigation certificates and notices.
406.18 Administration representatives.

SUBPART C—DENIAL OF CERTIFICATES

406.31 Denial of airman certificates.
406.32 Denial of airman, aircraft, air carrier, and air agency certificates.

SUBPART D—ALTERATION, AMENDMENT AND MODIFICATION OF CERTIFICATES

406.41 Initiation of proceedings.
406.42 Service of order to show cause.
406.43 Response to order to show cause.
406.44 Request for, or waiver of, hearing.
406.45 Notice of hearing.
406.46 Hearing.
406.47 Appearances.
406.48 Subpoenas.
406.49 Submission without hearing or appearance.
406.50 Stay of order pending judicial review.
406.51 Petition for rehearing, reargument, reconsideration, or modification of order.
406.52 Authority of examiners.

SUBPART E—SUSPENSION AND REVOCATION OF CERTIFICATES

406.61 Emergency suspensions.
406.62 Suspensions and revocations.

AUTHORITY: §§ 406.1 to 406.62 issued under sec. 205, 52 Stat. 984, as amended; 49 U. S. C. 425. Interpret or apply sec. 309, 602–609, 901, 1001–1009, 52 Stat. 1008–1011, 1015, 1017–1025, as amended, sec. 3, 62 Stat. 1217; 49 U. S. C. 552–559, 621, 641–649, 49 U. S. C. Sup. 459.

SUBPART A—INTRODUCTION

§ 406.1 *Definitions of terms.* As used in this part:

(a) "Act" shall mean Civil Aeronautics Act of 1938, as amended.

(b) "Administration" shall mean Civil Aeronautics Administration.

(c) "Administrator" shall mean Administrator of Civil Aeronautics.

(d) "Board" shall mean Civil Aeronautics Board.

§ 406.2 *Use of forms, etc.* Forms and other documents prescribed in this part which contain references to specific units of organization will not be affected by any changes in the titles of the units. Such forms and documents will continue in use until they have been superseded or revoked.

SUBPART B—ISSUANCE OF CERTIFICATES

§ 406.11 *General*—(a) *Application.* Except as otherwise indicated in this subpart, an application for a certificate may be obtained from, and shall be submitted to, a representative of the Administration or to one of its regional, district, or field offices.

(b) *Examination.* A medical examination where required will be given by a competent, licensed physician, or a designated medical examiner as indicated in this subpart. A theoretical or written examination where required will be given by an agent of the Administration, except that a student pilot may be examined on the Civil Air Regulations by a certificated flight instructor. Written examinations will be conducted at selected recognized airports. Itineraries of agents will be posted at such airports.

(c) *Issuance.* Requirements concerning the issuance of a certificate are set forth in Subchapter A of Chapter I of this title, or in this part.

§ 406.12 *Medical certificates.* The following medical certificates will be issued by the Administration to qualified applicants:

(a) *First-class medical certificate*—(1) *Purpose.* This certificate must be obtained by an applicant for an airline transport pilot rating.

(2) *Examination.* An examination for this certificate will be given by a designated airline medical examiner. A list of the designated airline medical examiners in any area may be obtained by addressing a request to the Regional Administrator of the region in which the area is located.

(3) *Issuance.* This certificate will be issued on a "Medical Certificate, Airline Transport Pilot," Form ACA–1004A.

(4) *Waiver.* An applicant for this certificate who does not meet the prescribed physical requirements, but has considerable aeronautical experience, may apply for a "Waiver of Physical Standards," Form ACA–779, from the Regional Administrator of the Region in which the applicant resides. A waiver will be issued if the applicant successfully demonstrates through a flight test that his physical deficiency is compensated for by his experience, ability, and judgment.

(5) *Additional requirements.* Further provisions regarding this certificate are contained in Part 29 of Chapter I of this title.

(b) *Second-class medical certificate*—(1) *Purpose.* This certificate must be obtained by an applicant for a commercial pilot rating, air-traffic control-tower operator certificate, flight navigator certificate, flight engineer certificate, or commercial lighter-than-air pilot certificate.

(2) *Examination.* An examination for this certificate will be given by a designated medical examiner. A list of the designated medical examiners in any area may be obtained by addressing a request to the Regional Administrator of the region in which the area is located.

(3) *Issuance.* This certificate will be issued on a "Medical Certificate, Commercial Airmen," Form ACA–1004.

(4) *Waiver.* An applicant for this certificate who does not meet the prescribed physical requirements, but has considerable aeronautical experience, may apply for a "Waiver of Physical Standards," Form ACA–779, from the Regional Administrator of the region in which the applicant resides. A waiver may be issued if the applicant successfully demonstrates through a flight test that his physical deficiency is compensated for by his experience, ability, and judgment.

(5) *Additional requirements.* Further provisions regarding this certificate

are contained in Part 29 of Chapter I of this title.

(c) *Third-class medical certificate.*—(1) *Purpose.* This certificate must be obtained by an applicant for a student pilot certificate, private pilot rating, student lighter-than-air pilot certificate, free balloon pilot certificate, and flight radio operator certificate.

(2) *Examination.* An examination for this certificate will be given by a designated medical examiner or a competent licensed physician. A list of the designated medical examiners in any area may be obtained by addressing a request to the Regional Administrator of the region in which the area is located.

(3) *Issuance.* This certificate will be issued on a "Medical Certificate, Student and Private Pilot," Form ACA–1005.

(4) *Waiver.* An applicant for this certificate who does not meet the prescribed physical requirements, but has considerable aeronautical experience, may apply for a "Waiver of Physical Standards," Form ACA–779, from the Regional Administrator of the region in which the applicant resides. A waiver may be issued if the applicant successfully demonstrates through a flight test that his physical deficiency is compensated for by his experience, ability, and judgment.

(5) *Additional requirements.* Further provisions regarding this certificate are contained in Part 29 of Chapter I of this title.

§ 406.13 *Airman certificates.* The following airman certificates will be issued by the Administration to qualified applicants.

(a) *Student pilot certificate*—(1) *Purpose.* This certificate will authorize the holder to pilot in solo flight, aircraft of a type, class, and model specified on the certificate.

(2) *Application.* A single application for this certificate will be made on an "Application for Pilot Certificate," Form ACA–355.

(3) *Issuance.* This certificate will be issued on a Form ACA–340.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Parts 20 and 43 of Chapter I.

(b) *Pilot certificate*—(1) *Purpose.* This certificate will authorize the holder to pilot aircraft in accordance with limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate with ratings shall be made on a "Pilot Flight Test Report," Form ACA–342a, or an "Application for Pilot Certificate," Form ACA–355, if for initial certification as a civilian pilot.

(3) *Issuance.* This certificate with ratings will be issued on a Form ACA–1710.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Parts 20 and 43 of Chapter I of this title.

(c) *Airline transport pilot certificate*—(1) *Purpose.* This certificate will authorize the holder to exercise the privileges of an airline transport pilot in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on a "Pilot Flight Test Report," Form ACA–342a.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 21 of Chapter I of this title.

(d) *Lighter-than-air pilot certificate*—(1) *Purpose.* This certificate will authorize the holder to exercise the privileges of a lighter-than-air pilot in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Pilot Certificate," Form ACA–355.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 22 of Chapter I of this title.

(e) *Mechanic certificate*—(1) *Purpose.* This certificate will authorize the holder to inspect, maintain, or repair aircraft and aircraft engines and appliances in accordance with the limitations set forth on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Airman Mechanic or Parachute Technician Certificate and Rating," Form ACA–363.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Reports.* The holder of this certificate shall submit a "Periodic Activity Report," Form ACA–1130, to the Administration annually during the month of January.

(5) *Additional requirements.* Further provisions regarding this certificate are contained in Part 24 of Chapter I of this title.

(f) *Parachute technician certificate*—(1) *Purpose.* This certificate will authorize the holder to inspect, pack, repair, or construct parachutes in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Airman Mechanic or Parachute Technician Certificate and Rating," Form ACA–363.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Reports.* The holder of this certificate shall submit a "Periodic Activity Report," Form ACA–1130, to the Administration annually during the month of January.

(5) *Additional requirements.* Further provisions regarding this certificate are contained in Part 25 of Chapter I of this title.

(g) *Air-traffic control-tower operator certificate*—(1) *Purpose.* This certificate will authorize the holder to control air traffic in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Control-Tower Operator or Aircraft Dispatcher Certificate and Rating," Form ACA–374.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 26 of Chapter I of this title.

(h) *Aircraft dispatcher certificate*—(1) *Purpose.* This certificate will authorize the holder to act as an aircraft dispatcher for a certificated air carrier in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Control-Tower Operator or Aircraft Dispatcher Certificate and Rating," Form ACA–374.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Reports.* The holder of this certificate shall submit a "Periodic Activity Report," Form ACA–1130 to the Administration annually during the month of January.

(5) *Additional requirements.* Further provisions regarding this certificate are contained in Part 27 of Chapter I of this title.

(i) *Flight radio operator certificate*—(1) *Purpose.* This certificate will authorize the holder to exercise the privileges of a flight radio operator in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Airman Certificate Flight Radio Operator, Flight Navigator, Flight Engineer," Form ACA–1770.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 33 of Chapter I of this title.

(j) *Flight navigator certificate*—(1) *Purpose.* This certificate will authorize the holder to exercise the privileges of a flight navigator in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Airman Certificate Flight Radio Operator, Flight Navigator, Flight Engineer," Form ACA–1770.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 34 of Chapter I of this tftle.

(k) *Flight engineer certificate*—(1) *Purpose.* This certificate will authorize the holder to exercise the privileges of a flight engineer in accordance with the limitations prescribed on the certificate.

(2) *Application.* A single application for this certificate shall be made on an "Application for Airman Certificate Flight Radio Operator, Flight Navigator, Flight Engineer," Form ACA–1770.

(3) *Issuance.* This certificate will be issued on a Form ACA–1710.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 35 of Chapter I of this title.

§ 406.14 *Aircraft certificates.* The following aircraft certificates will be

issued by the Administration to qualified applicants:

(a) *Type certificate*—(1) *Purpose.* This certificate will certify that an aircraft, aircraft engine, propeller, or appliance specified in the Civil Air Regulations as eligible for a type certificate is of proper design, material, specifications, construction, and performance for safe operation, and meets the minimum requirements of the Civil Air Regulations.

(2) *Application.* A single application for this certificate shall be made on an "Application for Type Certificate," Form ACA–312. This application form may be obtained from, and shall be submitted to the local Aviation Safety Agent, Aviation Safety District Office, or Aircraft Division of the regional office serving the area in which the manufacturer's plant is located.

(3) *Issuance.* This certificate will be issued on a Form ACA–331.

(4) *Reports.* Upon the initial transfer of title to any aircraft manufactured in accordance with Administration standards and requirements for United States registry, and where such aircraft has been manufactured under the terms of a type certificate only, i. e., without benefit of a production certificate, the holder of the type certificate or of a current right to the benefits of a type certificate under a licensing arrangement shall submit a "Statement of Conformity," Form ACA–317, to a duly authorized representative of the Administrator.

(5) *Additional requirements.* Further provisions regarding this certificate are contained in Part 2 of Chapter I of this title.

(b) *Production certificate*—(1) *Purpose.* This certificate will authorize duplicates of a product for which a type certificate has been issued, to be manufactured at designated places.

(2) *Application.* A single application for this certificate and a production limitation record, shall be made on an "Application for Production Certificate," Form ACA–332. The application form may be obtained from, and shall be submitted to, the Aircraft Division of the Regional Office serving the area in which the manufacturer's plant is located. If an amendment is desired, application shall be made to such Regional Office.

(3) *Issuance.* This certificate will be issued on a "Production Certificate," Form ACA–333. It will include a "Production Limitation Record," Form ACA–333a, which will set forth the applicable type certificate.

(4) *Reports.* The holder of this certificate shall notify the Regional Office which issued the certificate, of any changes in organization, methods, procedures, facilities, or location of the manufacturing facilities which affect the product for which the certificate was issued.

(5) *Additional requirements.* Further provisions regarding this certificate are contained in Part 2 of Chapter I of this title.

(c) *Aircraft registration certificate*—(1) *Purpose.* This certificate will satisfy the provisions of the act requiring that an aircraft be registered by its owner before it may be operated or navigated.

(2) *Application and fee.* An application for this certificate shall be made on a Form ACA–500. This form will contain three parts: Part A, "Certificate of Registration"; Part B, "Application for Registration"; and Part C, "Bill of Sale." An applicant for a registration certificate shall mail an original and a duplicate of Part A, a duplicate of Part B, an original of Part C or another bill of sale or a conditional sales contract, and a registration fee of $4 to the Aircraft Records Branch of the Administration in Washington, D. C. If a conditional sales contract is submitted, an additional fee of $4 shall be enclosed to record it. The applicant shall retain the original of Part B in the aircraft as a temporary registration for 30 days. A "Certificate of Ownership," Form ACA–1160, will no longer be issued by the Administration. However, such a certificate issued prior to November 15, 1946, may be used subsequent to that date in effecting the transfer of ownership of an aircraft if it is accompanied by a registration fee of $4. If such a form is outstanding but is not used in effecting the transfer of ownership, it should be surrendered at the time the next application is made on a Form ACA–500 for registration of the aircraft.

(3) *Issuance.* This certificate will be issued on the original "Certificate of Registration," Form ACA–500, Part A.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 501 of this chapter.

(d) *Dealers' aircraft registration certificate*—(1) *Purpose.* This certificate will provide an alternate form of registration permitting the operation, demonstration, and merchandising of civil aircraft moving in ordinary trade channels from a manufacturer, distributor, or dealer to an ultimate purchaser.

(2) *Application and fee.* An application for this certificate shall be made on an "Application for Issuance of Dealers' Aircraft Registration Certificate(s)," Form ACA–1706. It will require a statement of the dealer's citizenship and certain data concerning his status as a bona fide dealer in aircraft. An application containing current data shall be submitted each time certificates are requested, and may cover as many certificates as are desired at that time. This application may be obtained from, and shall be submitted to, the local Aviation Safety Agent, Aviation Safety District Office, or Aircraft Division of the regional office serving the area in which the applicant's business is located. A fee of $5 will be charged for the first certificate, and $1 for each additional or subsequent certificate issued to the same dealer.

(3) *Issuance.* This certificate will be issued on a "Dealers' Aircraft Registration Certificate," Form ACA–1707. It will be valid for 12 months from the date of issuance. Duplicates will not be issued.

(4) *Additional requirements.* Further provisions regarding the issuance and use of this certificate are contained in Part 502 of this chapter.

(e) *Aircraft airworthiness certificate*—(1) *Purpose.* This certificate will authorize the operation of a civil aircraft of United States registry within the United States, its territories, and its possessions. However, there shall be available in the aircraft an "Operation Limitations," Form ACA–309, or an approved airplane flight manual which sets forth the limitations for safe operation.

(2) *Application.* A single application for this certificate and an aircraft operation record shall be made on an "Application for Airworthiness Certificate and/or Annual Inspection of an Aircraft," Form ACA–305. Usually, the manufacturer obtains the certificate, which thereafter shall remain with the aircraft. If no airworthiness certificate has been issued for the aircraft, an application for such a certificate may be made by the registered owner of the aircraft, or his agent.

(3) *Issuance.* This certificate will be issued on a "Certificate of Airworthiness," Form ACA–1362 or Form ACA–1362a whichever is applicable.

(4) *Inspections.* An annual inspection of all certificated aircraft by an authorized representative of the Administrator is required unless the aircraft is being maintained and inspected by a continuous maintenance and inspection system. The aircraft and engine records must be maintained and kept available for inspection. (See Part 43 of Chapter I of this title.)

(f) *Ferry permit*—(1) *Purpose.* This permit will authorize the flight of a civil aircraft of United States registry between two specified points for the purpose of repairing, or obtaining certification of, an aircraft, or it will authorize an aircraft to be delivered via fly-away to a border of the United States or to some other point within the United States from which the aircraft is to be exported. (See § 43.10 (b) of Chapter I of this title.)

(2) *Application.* An application for this permit shall be made on an "Application and Authorization for Ferry Permit," Form ACA–1779. The applicant shall furnish evidence identifying the aircraft, reveal the points between which the aircraft will be flown, estimate duration of the flight, and furnish a statement giving the reasons why an aircraft airworthiness certificate is not applicable.

(3) *Issuance.* Normally, this permit will be issued on an "Application and Authorization for Ferry Permit," Form ACA-1779, but in some instances may be authorized by wire or telephone.

(g) *Foreign civil aircraft flight permit.*—(1) *Purpose.* This permit will authorize flight within the United States, its territories, and its possessions (except the Canal Zone) of foreign aircraft with foreign markings.[1]

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[1] Foreign civil aircraft of Contracting States to ICAO which are on (i) private flights for pleasure, or (ii) flights on the business of the individual or enterprise owning the aircraft when no valuable consideration of any kind is received for, or arising from the carriage of persons or property, or (iii) flight in transit on other than scheduled air services when no passengers, cargo or mail are to be discharged or embarked, may operate, without prior permission, into or within the United States or territory or possessions of United States subject to certain safety requirements.

(2) *Application.* An application for this certificate shall be made on an "Application for Foreign Civil Aircraft Flight Permit," Form ACA–776A. The application will require the itinerary (points of origination and termination, last point of landing prior to entering the United States, and landing points within the United States); estimated duration of flight in the United States; name and address of applicant; purpose of flight; description of aircraft, including foreign identification mark and country of registry; indication as to radio equipment installed in aircraft; type of operation (VFR or IFR flight) for which permission is requested; the cargo and passengers to be carried; flight crew information, and name and address of person to whom permit should be mailed. Form ACA–776A may be obtained from any regional or district office in the United States, from any international field office, or from the Civil Aeronautics Administration, Washington, D. C. For flights of a non-commercial nature, applications may be submitted to the Civil Aeronautics Administration, Washington, D. C., to the nearest Civil Aeronautics Administration international field office, or to the regional or district office of the Administration which is nearest to the port of entry. For flights involving commercial (non-common carrier) operations, applications must be submitted to the Civil Aeronautics Administration, Washington, D. C.

(3) *Issuance.* Permits involving non-commercial operations issued in the field will be issued on Form ACA–1452, "Foreign Civil Aircraft Flight Permit." Permits involving commercial (non-common carrier) operations issued by the Washington office are not contained on Form ACA–1452 because of the extra conditions and limitations involved but will be issued in the form of a letter.

(h) *Certificate of airworthiness for export*—(1) *Purpose.* This certificate will certify that the type-certificated product involved meets certain general and special requirements for export to particular foreign citizens or foreign countries.

(2) *Application.* An application for this certificate shall be made on an "Application for Certificate of Airworthiness for Export," Form ACA–306.

(3) *Issuance.* This certificate will be issued on a "Certificate of Airworthiness for Export," Form ACA–26.

§ 406.15 *Air carrier certificates.* The following air carrier certificates will be issued by the Administration to qualified applicants:

(a) *Air carrier operating certificate*—(1) *Purpose.* This certificate will describe the operations authorized, and prescribe such operation specifications and limitations as may reasonably be required in the interest of safety. It is required for all air carriers engaged in scheduled and irregular operations.

(2) *Application.* (i) An application for a scheduled air carrier operating certificate shall be made by letter to the regional office of the Administration serving the area in which the principal office of the air carrier is located.

(ii) An application for an irregular air carrier operating certificate shall be made on an "Application for Certificate to Operate as Irregular Air Carrier or Commercial Operator," Form ACA–1602, to the regional office serving the area in which the principal office of the air carrier is located.

(3) *Additional requirements.* Further provisions regarding this certificate are contained in Parts 40, 41, 42, and 61 of Chapter I of this title.

§ 406.16 *Air agency certificates.* The following air agency certificates and ratings will be issued by the Administration to qualified applicants:

(a) *Basic ground school rating.*—(1) *Purpose.* This rating will authorize the holder to operate as a basic ground school.

(2) *Application.* An application for this rating shall be made on an "Application for Airman Agency Certificate and Rating, and Inspection Report," Form ACA–387. A new application shall be submitted at least every two years.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Reports.* The holder of this rating shall submit an "Approved Air Agency Activity Report," Form ACA–1784, whenever it is able to report on 32 students, or at least every six months.

(5) *Additional requirements.* Further provisions regarding this rating are contained in Part 50 of Chapter I of this title.

(b) *Advanced ground school rating.*—(1) *Purpose.* This rating will authorize the holder to operate as an advanced ground school.

(2) *Application.* An application for this rating shall be made on an "Application for Airman Agency Certificate and Rating, and Inspection Report," Form ACA–387. A new application shall be submitted at least every two years.

(3) *Issuance.* This certificate will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Reports.* The holder of this rating shall submit an "Approved Air Agency Activity Report," Form ACA–1784, whenever it is able to report on 32 students, or at least every six months.

(5) *Additional requirements.* Further provisions regarding this rating are contained in Part 50 of Chapter I of this title.

(c) *Primary flying school rating*—(1) *Purpose.* This rating will authorize the holder to operate as a primary flying school.

(2) *Application.* An application for this rating shall be made on an "Application for Airman Agency Certificate and Rating, and Inspection Report," Form ACA–387. A new application shall be submitted at least every two years.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Reports.* The holder of this rating shall submit an "Approved Air Agency Activity Report," Form ACA–1784, whenever it is able to report on 32 students or at least every six months.

(5) *Additional requirements.* Further provisions regarding this rating are contained in Part 50 of Chapter I of this title.

(d) *Commercial flying school rating*—(1) *Purpose.* This rating will authorize the holder to operate as a commercial flying school.

(2) *Application.* An application for this rating shall be made on an "Application for Airman Agency Certificate and Rating, and Inspection Report," Form ACA–387. A new application shall be submitted at least every two years.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Reports.* The holder of this rating shall submit an "Approved Air Agency Activity Report," Form ACA–1784, whenever it is able to report on 32 students or at least every six months.

(5) *Additional requirements.* Further provisions regarding this rating are contained in Part 50 of Chapter I of this title.

(e) *Instrument flying school rating*—(1) *Purpose.* This rating will authorize the holder to operate as an instrument flying school.

(2) *Application.* An application for this rating shall be made on an "Application for Airman Agency Certificate and Rating, and Inspection Report," Form ACA–387. A new application shall be submitted at least every two years.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Reports.* The holder of this rating shall submit an "Approved Air Agency Activity Report," Form ACA–1784, whenever it is able to report on 32 students, or at least every six months.

(5) *Additional requirements.* Further provisions regarding this rating are contained in Part 50 of Chapter I of this title.

(f) *Flight instructor school rating*—(1) *Purpose.* This rating will authorize the holder to operate as a flight instructor school.

(2) *Application.* An application for this rating shall be made on an "Application for Airman Agency Certificate and Rating, and Inspection Report," Form ACA–387. A new application shall be submitted at least every two years.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Reports.* The holder of this rating shall submit an "Air Agency Activity Report," Form ACA–1784, whenever it is able to report on 32 students or at least every six months.

(5) *Additional requirements.* Further provisions regarding this rating are contained in Part 50 of Chapter I of this title.

(g) *Repair station rating*—(1) *Purpose.* This rating will authorize the holder to operate as a repair station.

(2) *Application.* An application for this rating shall be made on an "Application for Aircraft Repair Station," Form ACA–394.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Additional requirements.* Further provisions regarding this rating are contained in Part 52 of Chapter I of this title.

(h) *Mechanic school rating*—(1) *Purpose.* This rating will authorize the holder to operate as a mechanic school.

(2) *Application.* An application for this rating shall be made on a "Mechanic School Application and Inspection Report," Form ACA–614.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Reports.* The holder of this rating shall submit a "Mechanic School Report," Form ACA–392, in January and July of every year.

(5) *Additional requirements.* Further provisions regarding this rating are contained in Parts 50 and 53 of Chapter I of this title.

(i) *Parachute loft rating*—(1) *Purpose.* This rating will authorize the holder to operate as a parachute loft.

(2) *Application.* An application for this rating shall be made on an "Application for Parachute Loft Certificate and Rating," Form ACA–1371.

(3) *Issuance.* This rating will be issued on an "Air Agency Certificate," Form ACA–390.

(4) *Additional requirements.* Further provisions regarding this rating are contained in Part 54 of Chapter I of this title.

(j) *Ground instructor certificate and rating*—(1) *Purpose.* This certificate and rating will authorize the holder to serve as a ground instructor.

(2) *Application.* An application for this certificate and rating shall be made on an "Application for Ground Instructor Certificate or Rating," Form ACA–360.

(3) *Issuance.* This certificate and rating will be issued on a Form ACA–1710.

(4) *Reports.* The holder of this certificate and rating shall submit a "Periodic Activity Report," Form ACA–1130, to the Administration each year during the month of January.

(5) *Additional requirements.* Further provisions regarding this certificate and rating are contained in Parts 50 and 51 of Chapter I of this title.

(k) *Commercial operator certificate*—(1) *Purpose.* This certificate will authorize the holder to serve as a commercial operator.

(2) *Application.* An application for this certificate shall be made on an "Application for Certificate to Operate as Irregular Air Carrier or Commercial Operator," Form ACA–1602.

(3) *Issuance.* This certificate will be issued on a Form ACA–1603.

(4) *Additional requirements.* Further provisions regarding this certificate are contained in Part 45 of Chapter I of this title.

§ 406.17 *Air navigation certificates and notices.* The following air navigation certificates will be issued by the Administration to qualified applicants and the following air navigation notices are required:

(a) *Authorization to operate true light*—(1) *Purpose.* This certificate will authorize the holder to operate an aeronautical light as a "true light."

(2) *Application.* An application for this certificate shall be submitted on an "Application for Rating of Air Navigation Facility and Lawful Authority to Operate a 'True Light' ", Form ACA–114.

(3) *Issuance.* A temporary certificate, good for a period of 60 days, will be issued by the Regional Office serving the region in which the facility is located. A permanent certificate will be issued by the Washington Office on an "Air Navigation Facility Certificate," Form ACA–115.

(b) *Notice of construction or alteration*—(1) *Purpose.* This notice must be submitted to the Administrator in order that he may give proper notice to airmen of the construction or alteration of a structure located along or near a civil airway.

(2) *Submittal.* Notice shall be submitted to the Administrator on a "Notice of Construction or Alteration of Structures, or Construction of New Landing Areas," Form ACA–117.

(3) *Additional requirements.* Further provisions regarding notices of construction or alteration are contained in Part 625 of this chapter.

§ 406.18 *Administration representatives.* The following certificates may be issued by the Administration to qualified applicants in order that they may assist the Administration in performing the functions indicated.

(a) *Pilot examiner certificate*—(1) *Purpose.* This certificate will authorize the holder to act as a pilot examiner for the Administration and to conduct flight examinations for the issuance of pilot certificates and ratings.

(2) *Application.* An application for this certificate shall be made on a "Pilot Examiner Qualification Record and Flight Test Report," Form ACA–914.

(3) *Issuance.* This certificate will be issued on a "Certificate of Authority," Form ACA–1382.

(4) *Reports.* The holder of this certificate shall execute and submit in duplicate monthly, a "Flight Test Activity Report," Form ACA–857, to his Regional Office through his supervising agent.

(b) *Air crew examiner certificate*—(1) *Purpose.* This certificate will authorize the holder to act as a flight radio operator examiner, flight navigator examiner, flight engineer examiner, as indicated on the certificate, and to conduct flight examinations for the certificates.

(2) *Application.* An application for this certificate shall be made on a "Statement of Qualifications and Designation-Air Crew Examiner," Form ACA–1861.

(3) *Issuance.* This certificate will be issued on a "Certificate of Authority," Form ACA–1382.

(4) *Reports.* The holder of this certificate shall execute and submit to his supervising agent a "Flight Test Activity Report," Form ACA–857, for each calendar year.

(c) *Medical examiner certificate*—(1) *Purpose.* This certificate will authorize the holder to give physical examinations required for the issuance of medical certificates.

(2) *Application.* An application for this certificate shall be made on an "Application for Designation as Medical Examiner," Form ACA–861, and shall be submitted to a regional medical officer of the Administration serving the area in which the applicant practices medicine.

(3) *Issuance.* This certificate will be issued on an "Authorized Medical Examiner and Letter of Designation," Form ACA–1668.

(4) *Reports.* A "Report of Physical Examination for Airmen Certificate," Form ACA–358, or "Report of Physical Examination for Air-Line Transport Pilot," Form ACA–359, shall be submitted within 48 hours after examination to the Regional Administrator serving the region in which the applicant is examined. A copy of the report must be retained in the file of the designated medical examiner for three years.

(d) *Mechanic examiner certificate*—(1) *Purpose.* This certificate will authorize the holder to conduct oral and practical examinations for the issuance of aircraft mechanic and aircraft engine mechanic certificates.

(2) *Application.* An application for this certificate shall be made on a "Statement of Qualifications and Recommendations for Designated Mechanic Examiner," Form ACA–1618.

(3) *Issuance.* This certificate will be issued on a "Certificate of Authority," Form ACA–1382.

(e) *Manufacturing representative certificate*—(1) *Purpose.* This certificate will authorize the holder to determine the conformity and quality of products manufactured by his employer under the terms of a production certificate, and to issue airworthiness certificates for aircraft and certificates of airworthiness for export for aeronautical products manufactured under the terms of the production certificate.

(2) *Application.* An application for this certificate shall be made on a "Statement of Qualifications for Designated Manufacturing Inspection Representatives," Form ACA–1381. It shall be transmitted to the local agent of the Administration, with a letter of recommendation from the employing manufacturer.

(3) *Issuance.* This certificate will be issued on a "Certificate of Authority," Form ACA–1382.

(f) *Engineering representative certificates*—(1) *Purpose.* These certificates will authorize the holder to certify that certain engineering data pertaining to certification of an aircraft or aircraft component, or pertinent to the maintenance, repair, or alteration of aircraft or aircraft component complies with the Civil Air Regulations.

(2) *Application.* An application for this certificate shall take the form of a letter from the nominee's employer requesting the appointment of the nominee as a designated engineering representative. This letter shall be accompanied by a Form ACA–1599, "Statement of Qualifications," executed by the nominee.

(3) *Issuance.* Two certificates will be issued the designee, a "Certificate of Designation," Form ACA–2001, and a

"Certificate of Authority," Form ACA-1382.

(4) *Termination of designee's authority.* The designee's authorization shall terminate:

(i) At the written request of the designee or his employer.

(ii) In the event that the designee leaves the employ of the employer by whom he was nominated.

(iii) If, after proper investigation, it is determined that the designee has made improper use of, or was careless or incompetent in the exercise of, his authority or responsibility.

SUBPART C—DENIAL OF CERTIFICATES

§ 406.31 *Denial of airman certificate.* Under section 602 (b) of the act, any person whose application for the issuance or renewal of an airman certificate is denied may file with the Board a petition for reconsideration, and the Board shall thereupon assign such application for hearing at a place convenient to the applicant's place of residence or employment.

§ 406.32 *Denial of airman, aircraft, air carrier, air navigation, or air agency certificate.* Under section 1006 of the act, any person disclosing a substantial interest in any order (except certain orders regarding foreign air carriers) denying the issuance or renewal of an airman, aircraft, air carrier, air navigation, or air agency certificate may appeal such order to a circuit court of appeals of the United States or the United States Court of Appeals for the District of Columbia, within 60 days after the entry of such order.

SUBPART D—ALTERATION, AMENDMENT, AND MODIFICATION OF CERTIFICATES

§ 406.41 *Initiation of proceedings.* A proceeding to alter, amend, or modify a certificate may be initiated by the Administrator or his authorized representative by the issuance of an order addressed to the certificate holder or other party in interest, directing him to show cause why the certificate should not be altered, amended, or modified as specified in the order.

§ 406.42 *Service of order to show cause.* The order to show cause will be served upon the party in interest by mailing a copy thereof by registered mail, return receipt requested, addressed to the party at his last known address.

§ 406.43 *Response to order to show cause.* After service upon him of the order to show cause, the respondent will have ten days within which to respond in writing to the order. Such answer will be deemed filed as of the date of mailing to the General Counsel of the Administration, properly addressed and postage prepaid. If respondent fails to answer the order within ten days, the Administrator or the Examiner assigned to hear the matter may forthwith order that the certificate be amended in accordance with the show cause order.

§ 406.44 *Request for, or waiver of, hearing.* The respondent will have the right to have the matter set for hearing and the issue determined on the basis of the facts presented at such hearing. If respondent fails to request a hearing within ten days after serving of the order to show cause, the issues may be decided upon the basis of facts and arguments presented in writing by the respondent and the counsel assigned to represent the Federal Government.

§ 406.45 *Notice of hearing.* When a hearing has been requested, the respondent will be given adequate notice of the date and place where such hearing will be held. In fixing the times and places for hearings, due regard will be had for the convenience and necessity of the parties and their representatives.

§ 406.46 *Hearing.* A hearing will be held before an Examiner duly designated by the Administrator.

§ 406.47 *Appearances.* Any party to a proceeding may appear and be heard in person or by attorney. No register of attorneys who may practice before the Administrator will be maintained and no application for admission to practice will be required. Any attorney practicing or desiring to practice before the Administrator may, upon hearing and good cause shown, be suspended or prohibited from so practicing.

§ 406.48 *Subpoenas.* Subpoenas requiring the attendance of witnesses, or the production of evidence, at a designated place of hearing, will be issued to any party to a proceeding upon proper application to the Examiner.

§ 406.49 *Submission without hearing or appearance.* Where respondent does not request a hearing, the Examiner, on the basis of the pleadings and the documentary evidence submitted by the parties, will prepare an initial decision. A copy of the initial decision will be served upon the respondent or his counsel, by personal service or registered mail. The parties to the proceedings will have ten days, or such other time as the Examiner may specify, after the date of service of such initial decision within which to file exceptions and appeal to the Administrator. If no appeal to the Administrator is filed or action by the Administrator to review such decision is entered within the time allowed, such decision will without further proceedings become the decision of the Administrator.

§ 406.50 *Stay of order pending judicial review.* The filing of a petition for a judicial review of an order made under this part as provided in section 1006 of the act will not operate to stay the effectiveness of the order unless specifically so ordered by the Administrator. The petitioner may request, and if good cause is shown therefor, the Administrator will stay the effectiveness of the order from which an appeal is being taken.

§ 406.51 *Petition for rehearing, reargument, reconsideration or modification of order.* (a) Either party to a proceeding may petition for rehearing, reargument, reconsideration or modification of any final order of the Administrator within ten days after receipt thereof.

(b) The filing of a petition to rehear or reargue a proceeding or to reconsider or modify an order, will not operate to stay the effectiveness of the order, unless otherwise ordered by the Administrator.

§ 406.52 *Authority of examiners.* Examiners will have authority as follows:

(a) To give notice concerning, and hold, hearings;

(b) To administer oaths and affirmations;

(c) To examine witnesses;

(d) To take or cause depositions to be taken whenever the ends of justice would be served thereby;

(e) To rule upon offers of proof and receive competent evidence;

(f) To regulate the course of the hearing;

(g) To hold conferences, before or during the hearing, for the settlement or simplification of issues, by consent of the parties;

(h) To dispose of procedural requests or similar matters;

(i) Within his discretion, or upon the direction of the Administrator, to certify any question to the Administrator for his consideration and disposition;

(j) To issue subpoenas;

(k) To make initial decisions.

SUBPART E—SUSPENSION AND REVOCATION OF CERTIFICATES

§ 406.61 *Emergency suspensions.* See § 408.25 of this chapter.

§ 406.62 *Suspensions and revocations.* See § 408.26 of this chapter.

This part shall become effective upon publication in the FEDERAL REGISTER.

[SEAL] DONALD W. NYROP,
Administrator of Civil Aeronautics.

[F. R. Doc. 50-12475; Filed, Dec. 29, 1950; 8:58 a. m.]

PART 407—RECORDATION PROCEDURES

Under sections 205 and 501–503 of the Civil Aeronautics Act of 1938, as amended, the Administrator of Civil Aeronautics is empowered (1) to record instruments which affect interests in aircraft, aircraft engines, propellers, appliances, and parts, and (2) to make and amend such general or special procedures as he deems necessary to exercise and perform such powers and duties.

Acting pursuant to the foregoing authority, and in accordance with section 3 of the Administrative Procedure Act, I hereby revise Part 407 of this chapter to read:

SUBPART A—INTRODUCTION

Sec.
407.1 Definitions of terms.
407.2 Use of forms, etc.

SUBPART B—AIRCRAFT OWNERSHIP

407.11 General.
407.12 Forms of conveyance.
407.13 Application.
407.14 Recording fee.
407.15 Additional requirements.

SUBPART C—ENCUMBRANCES AGAINST SPECIFICALLY IDENTIFIED AIRCRAFT ENGINES

407.21 General.
407.22 Forms of conveyance.
407.23 Recording fee.
407.24 Additional requirements.

SUBPART D—ENCUMBRANCES AGAINST AIRCRAFT ENGINES, PROPELLERS, APPLIANCES, OR SPARE PARTS

Sec.
407.31 General.
407.32 Forms of conveyance.
407.33 Recording fee.
407.34 Additional requirements.

AUTHORITY: §§ 407.1 to 407.34 issued under sec. 205, 52 Stat. 984, as amended; 49 U. S. C. 425. Interpret or apply secs. 501–503, 52 Stat. 1005, 1006, as amended; 49 U. S. C. 521–523.

SUBPART A—INTRODUCTION

§ 407.1 *Definitions of terms.* As used in this part:

(a) "Act" shall mean Civil Aeronautics Act of 1938, as amended.

(b) "Administration" shall mean Civil Aeronautics Administration.

§ 407.2 *Use of forms, etc.* Forms and other documents prescribed in this part which contain references to specific units of organization will not be affected by any changes in the titles of the units. Such forms and documents will continue in use until they have been superseded or revoked.

SUBPART B—AIRCRAFT OWNERSHIP

§ 407.11 *General.* All conveyances which affect the title to, or any interest in, an aircraft registered under the provisions of the act are eligible for recordation with the Administration. A receipt showing recordation of any document evidencing indebtedness will be furnished by the Administration to the holder of such a document.

§ 407.12 Forms of conveyance. The following forms have been prepared by the Administration for use in recording conveyances, and will be available upon request to the Aircraft Recordation Branch of the Administration in Washington, D. C.:

(a) "Bill of Sale," Form ACA–500, Part C. Further information concerning Form ACA–500 is contained in § 406.14 (c) of this chapter.

(b) "Release," Form ACA–506. This form appears on the back of a letter acknowledging receipt of a chattel mortgage, and should be in the possession of the mortgagee or his assignee, to be used when the mortgage is clear.

(c) "Release Contract of Conditional Sale," Form ACA–818. This form appears on the back of a letter acknowledging receipt of a contract of conditional sale, and should be in the possession of the seller or his assignee, to be used when all conditions of the contract have been met.

(d) "Aircraft Chattel Mortgage," Form ACA–905.

(e) "Aircraft Conditional Sale Contract," Form ACA–906.

(f) "Supplemental Affidavit to Application for Registration of all Types of Aircraft," Form ACA–909. This form shall be filled in and submitted with the "Application for Registration," Form ACA–500, Part B, when the aircraft has been repossessed pursuant to the provisions of a chattel mortgage or contract of conditional sale, and the person repossessing desires registration of the aircraft in his name.

§ 407.13 *Application.* A conveyance may be recorded by submitting the original document or a properly executed duplicate of the document to the Aircraft Records Branch of the Administration in Washington, D. C.

§ 407.14 *Recording fee.* There will be no fee other than the $4 registration fee for recording a bill of sale. A fee of $4 will be charged for recording a lien covering one aircraft. If more than one aircraft is covered by a lien, the fee will be $4 for each aircraft covered. Fees shall be submitted in the form of a check or money order, made payable to the Treasurer of the United States. No fee will be required for recording a release, cancellation, discharge, or satisfaction relating to a lien covering an aircraft.

§ 407.15 *Additional requirements.* Further provisions regarding the recordation of aircraft ownership are contained in Part 503 of this chapter.

SUBPART C—ENCUMBRANCES AGAINST SPECIFICALLY IDENTIFIED AIRCRAFT ENGINES

§ 407.21 *General.* All conveyances which affect the title to, or any interest in, a specifically identified aircraft engine or engines of 750 or more rated take-off horsepower for each such engine or the equivalent of such horsepower, are eligible for recordation with the Administration. A receipt showing recordation of any such conveyance will be furnished by the Administration to the holder of such documents.

§ 407.22 *Forms of conveyance.* The Administration has not prepared any sample forms of conveyance for use in taking a security interest in aircraft engines. However, Form ACA–1990 has been designed to serve as a receipt for recording aircraft engine conveyances.

§ 407.23 *Recording fee.* A fee of $2 will be charged for recording a document executed for security purposes covering one engine. If more than one aircraft engine is covered by such document, the fee will be $2 for each aircraft engine covered. Fees shall be submitted in the form of a check or money order made payable to the Treasurer of the United States. No fee will be required for recording a release, cancellation, discharge, or satisfaction relating to a conveyance covering an aircraft engine.

§ 407.24 *Additional requirements.* Further provisions regarding the recordation of encumbrances against specifically identified aircraft engines are contained in Part 504 of this chapter.

SUBPART D—ENCUMBRANCES AGAINST AIRCRAFT ENGINES, PROPELLERS, APPLIANCES, OR SPARE PARTS

§ 407.31 *General.* All conveyances affecting title to, or any interest in aircraft engines, propellers, or appliances maintained by or on behalf of an air carrier certificated under section 604 (b) of the act for installation or use in aircraft, aircraft engines, or propellers, or any spare parts maintained by or on behalf of such an air carrier, which documents need only describe generally by types, the engines, propellers, appliances, and spare parts covered by the documents, and designate the location or locations of the engines, etc., will be eligible for recordation with the Administration. A receipt showing recordation of any such conveyance will be furnished by the Administration to the holder of such a document.

§ 407.32 *Forms of conveyance.* The Administration has not prepared any sample forms of conveyance for use in taking a security interest in aircraft engines, propellers, appliances, or spare parts. However, Form ACA–1991 has been designated to serve as a receipt for recording such a conveyance.

§ 407.33 *Recording fee.* A fee of $2 will be charged for recording a document executed for security purposes, covering aircraft engines, propellers, appliances, or spare parts located in one place. If the property covered by the document is located in more than one place, the fee will be $2 for each location. Fees shall be submitted in the form of a check or money order made payable to the Treasurer of the United States. No fee will be required for recording a release, cancellation, discharge, or satisfaction relating to a conveyance covering aircraft engines, propellers, appliances, or spare parts.

§ 407.34 *Additional requirements.* Further provisions regarding the recordation of encumbrances against aircraft engines, propellers, appliances, or spare parts are contained in Part 505 of this chapter.

This part shall become effective upon publication in the FEDERAL REGISTER.

[SEAL] DONALD W. NYROP,
Administrator of Civil Aeronautics.

[F. R. Doc. 50–12476; Filed, Dec. 29, 1950; 8:46 a. m.]

PART 408—ENFORCEMENT PROCEDURES

Under sections 205, 609, 901, 903, and 1002 of the Civil Aeronautics Act of 1938, as amended, the Administrator of Civil Aeronautics is empowered (1) to administer and enforce provisions of the Act and rules, regulations, and certificates issued pursuant to such provisions, and (2) to make and amend such general or special procedures as he deems necessary to exercise and perform such powers and duties.

Acting pursuant to the foregoing authority, and in accordance with section 3 of the Administrative Procedure Act, I hereby adopt Part 408 of this chapter, to read:

SUBPART A—INTRODUCTION

Sec.
408.1 Definitions of terms.

SUBPART B—PROCESSES USED IN ENFORCEMENT

408.11 Report channels.

SUBPART C—ACTIONS TAKEN IN ENFORCEMENT

408.21 Records.
408.22 Reprimands.
408.23 Civil penalties.
408.24 Seizures of aircraft.
408.25 Emergency suspensions.
408.26 Complaints.
408.27 Military actions.
408.28 Criminal penalties.

AUTHORITY: §§ 408.1 to 408.28 issued under sec. 205, 52 Stat. 984, as amended; 49 U. S. C. 425. Interpret or apply secs. 609, 901, 903, 1002, 52 Stat. 1011, 1015, 1017, 1018, as amended; 49 U. S. C. 559, 621, 623, 642.

SUBPART A—INTRODUCTION

§ 408.1 *Definitions of terms.* As used in this part:

(a) "Act" shall mean Civil Aeronautics Act of 1938, as amended.

(b) "Administration" shall mean Civil Aeronautics Administration.

(c) "Administrator" shall mean Administrator of Civil Aeronautics.

(d) "Board" shall mean Civil Aeronautics Board.

SUBPART B—PROCESSES USED IN ENFORCEMENT

§ 408.11 *Report channels.* Apparent violations of the act or regulations issued thereunder should be reported by any person having knowledge of such violations, to a representative of the Administration assigned to one of its regional or district offices. A report of apparent violations will be investigated by an appropriate representative of the Administration, and the results of such investigation will constitute the basis for determining appropriate action to be taken by the Administration.

SUBPART C—ACTIONS TAKEN IN ENFORCEMENT

§ 408.21 *Records.* A report of violations may be filed for record if it appears after investigation by the Administration that the apparent violations were inadvertently committed, were of an insignificant nature, and/or will not be repeated by the alleged violator.

§ 408.22 *Reprimands.* A letter may be sent to the alleged violator reprimanding him for minor violations he is reported to have committed, and pointing out to him that the report will be considered in determining the appropriate action to be taken regarding any future violations reported against him.

§ 408.23 *Civil penalties.* Under section 901 of the act, any person who violates any provisions of Titles V, VI, or VII of the act, or section 11 (a) (1) of the Air Commerce Act of 1926, as amended, shall be subject to a civil penalty, and such penalty generally may be compromised by the Administrator. In the event imposition of a civil penalty is contemplated by the Administrator, and it is considered advisable to compromise the amount of such penalty, the Regional Attorney serving the Region of the Administration in which the violations are believed to have occurred, or the General Counsel of the Administration if a scheduled air carrier is involved, will send a letter to the alleged violator, advising what statutes and regulations seem to have been violated, and affording an opportunity to compromise the civil penalties resulting from the apparent violations. The alleged violator may submit to the official signing the notice of civil penalty, either orally or in writing, any material or information in answer to or tending to explain, mitigate, or extenuate the apparent violation. Any material or information thus submitted will be considered in making final determination of the amount for which the civil penalties will be compromised. If an offer is tendered to compromise the penalties for a specific amount, and a certified check or money order in that amount, made payable to the Treasurer of the United States, is attached, the offer will be submitted to the Administrator with a recommendation regarding its acceptance. The Administrator in any case, or a Deputy Administrator in any case except one involving a scheduled air carrier, will accept or refuse the offer of compromise. If the offer of compromise is accepted, the alleged violator will be notified by a letter of its acceptance, and that such acceptance constitutes full settlement of any civil penalties due under the statutes and regulations by reason of the apparent violations. If a compromise settlement of the civil penalties cannot be effected, the Administration will, in an appropriate case, instigate the filing of a civil complaint in the United States District Court, pursuant to section 903 of the act, for the purpose of obtaining judicial determination of the civil penalties due.

§ 408.24 *Seizures of aircraft*—(a) *Authority to seize aircraft.* Whenever an aircraft is involved in a violation of any provision of Titles V and VI of the Civil Aeronautics Act of 1938, as amended, or of section 11 (a) (1) of the Air Commerce Act of 1926, as amended, or of any rule or regulation issued pursuant thereto, and the violation is committed by the owner or person in command of the aircraft, such aircraft may be summarily seized by any state or Federal law enforcement officer or Federal aviation safety agent authorized in an order of seizure issued by the Regional Administrator of the region in which the aircraft is located.

(b) *Custody of seized aircraft.* Whenever an aircraft has been seized pursuant to this section, it will be placed in the nearest available adequate public storage facility in the judicial district in which the seizure is made.

(c) *Notice of seizure.* Whenever an aircraft has been seized pursuant to this section, a written notice and a copy of this section will be sent without delay by the Regional Administrator to the registered owner of, and to other persons having a recorded interest in, the aircraft. The written notice will state:

(1) The time, date, and place of seizure;

(2) The name and address of the custodian of the aircraft;

(3) The reasons for the seizure, including the violations believed, or judicially determined, to have been committed; and

(4) The amount which may be tendered:

(i) As an offer in compromise of any civil penalties which might have been incurred as a result of the alleged violation, or

(ii) As payment of civil penalties which have been imposed by a Federal court as a result of the established violations.

(d) *Report of seizure.* Whenever an aircraft has been seized pursuant to this section, a report of the cause will be transmitted immediately by the Regional Administrator to the United States Attorney for the judicial district in which the seizure is made, requesting the United States Attorney to institute proceedings for the enforcement of the lien.

(e) *Release of seized aircraft.* Whenever an aircraft has been seized pursuant to this section, it will be released by direction of the Regional Administrator under any one of the following conditions:

(1) Upon payment of the civil penalty or the amount agreed upon in compromise, and the costs incurred in connection with the seizure, storage, and maintenance of the aircraft;

(2) Upon seizure of the aircraft pursuant to process of a Federal court in proceedings in rem for enforcement of a lien against the aircraft, or notification by the United States Attorney of failure to institute such proceedings; or

(3) Upon deposit of a bond in such amount and with such sureties as the Regional Administrator may prescribe, conditioned upon payment of the penalty or the amount agreed upon in compromise, and the costs incurred in connection with the seizure, storage, and maintenance of the aircraft.

§ 408.25 *Emergency suspensions.* Under section 609 of the act, in cases of emergency a type certificate, production certificate, airworthiness certificate, airman certificate, air carrier operating certificate, air navigation facility certificate, or air agency certificate may be suspended, in whole or in part, for a period not in excess of 30 days, without regard to any requirement as to notice and hearing; the Administration shall immediately give notice of such suspension to the holder of such certificate, and shall enter upon a hearing which shall be disposed of as speedily as possible; and during the pendency of the proceeding the Administration may further suspend such certificate, in whole or in part, for an additional period not in excess of 30 days. In the event the condition or conduct of a certificate holder is such as to indicate immediate danger of injury to a person or damage to property, and the immediate suspension of the certificate might reasonably be expected to avert such injury or damage, an emergency will be deemed to exist within the meaning of section 609. Under such circumstances, any employee of the Administration charged with the duty of examining a certificate holder or enforcing aeronautical statutes and regulations,

may suspend for a period not to exceed 30 days, any of the foregoing certificates issued by the Administration other than an air carrier operating certificate, which may be suspended in an emergency only by the Administrator. Any such employee of the Administration making an emergency suspension will, if practicable, notify orally the party or parties involved, that an emergency suspension of the certificate has been made pursuant to the authority of section 609, and will, within a reasonable time thereafter, confirm such notification in writing. Formal proceedings will be instituted immediately, during the pendency of which the Administrator, a Deputy Administrator, or the Regional Administrator serving the region in which the condition is likely to exist or conduct is likely to occur, may further suspend such certificate, in whole or in part, for an additional period not in excess of 30 days.

§ 408.26 *Complaints.* Under section 1002 of the act, the Administration may file with the Board a complaint in writing, with respect to anything done or omitted to be done by any person in contravention of any provision of the act or any requirement established pursuant to the act. Under section 609 of the act, the Board may suspend, in whole or in part, any type certificate, production certificate, airworthiness certificate, airman certificate, air carrier operating certificate, air navigation facility certificate, or air agency certificate issued by the Administration, if the interest of the public so requires, or it may revoke, in whole or in part, any such certificate for any cause which at the time of revocation would justify the Administration in refusing to issue to the holder of such certificate a like certificate. After such a complaint has been filed, the Board will determine administratively whether a certificate issued by the Administration to the alleged violator shall be suspended or revoked. When such a procedure is used, the complaint will be prepared by the Regional Attorney of the Administration serving the area in which the violations are alleged to have been committed, or by the General Counsel of the Administration in the event a scheduled air carrier is involved, and filed with the Docket Section of the Board. Proceedings will be conducted in accordance with Part 301 of this title.

§ 408.27 *Military actions.* Where a report reveals that violations involving an aircraft of one of the United States armed forces have been committed, copies of the report will be forwarded by the Administration to the appropriate military authorities in order that they may take such disciplinary actions as they consider appropriate.

§ 408.28 *Criminal penalties.* Under section 902 of the act, any person who knowingly and willfully violates any provision of the act (except Titles V, VI, and VII) or any order, rule, or regulation issued under any such provision, for which no penalty is otherwise provided in the act, shall be deemed guilty of a misdemeanor and upon conviction thereof shall be subject to a fine. Under section 902, any person who knowingly and willfully forges, counterfeits, alters, or falsely makes any certificate authorized to be issued under the act, or knowingly uses or attempts to use any such fraudulent certificate shall be deemed guilty of a misdemeanor and upon conviction thereof shall be subject to a fine and/or imprisonment. Under section 902, any person who, with intent to interfere with air navigation within the United States, exhibits within the United States any light or signal in such place or in such manner that it is likely to be mistaken for a true light or signal established pursuant to the act, or for a true light or signal in connection with an airport or other air navigation facility; or after due warning by the Administrator continues to maintain any misleading light or signal; or knowingly removes, extinguishes, or interferes with the operation of, any such true light or signal shall be subject to a fine and/or imprisonment. If it appears from a report received by the Administration that any of these offenses has been committed, the Administration will, in an appropriate case, send the report to the Department of Justice for criminal prosecution of the person who committed the offense.

This part shall become effective upon publication in the FEDERAL REGISTER.

[SEAL] DONALD W. NYROP,
Administrator of Civil Aeronautics.

[F. R. Doc. 50-12477; Filed, Dec. 29, 1950; 8:46 a. m.]

[Amdt. 38]

PART 600—DESIGNATION OF CIVIL AIRWAYS

CIVIL AIRWAY ALTERATION

The civil airway alteration appearing hereinafter has been coordinated with the civil operators involved, the Army, the Navy, and the Air Force, through the Air Coordinating Committee, Airspace Subcommittee, and is adopted when indicated in order to promote safety of the flying public. Compliance with the notice, procedures, and effective date provisions of section 4 of the Administrative Procedure Act would be impracticable and contrary to public interest, and therefore is not required. Part 600 is amended as follows:

1. Section 600.101 *Amber civil airway No. 1 (United States-Mexican Border to Nome, Alaska)* is amended after "Toledo, Wash., radio range station" by adding the following: "excluding the Fort Lewis, Wash., danger area;".

(Sec. 205, 52 Stat. 984, as amended; 49 U. S. C. 425. Interprets or applies sec. 302, 52 Stat. 985, as amended; 49 U. S. C. 452)

This amendment shall become effective 0001, e. s. t., January 1, 1951.

[SEAL] DONALD W. NYROP,
Administrator of Civil Aeronautics.

[F. R. Doc. 50-12472; Filed, Dec. 29, 1950; 8:45 a. m.]

[Amdt. 41]

PART 601—DESIGNATION OF CONTROL AREAS, CONTROL ZONES, AND REPORTING POINTS

MISCELLANEOUS AMENDMENTS

The control area and reporting point alterations appearing hereinafter have been coordinated with the civil operators involved, the Army, the Navy and the Air Force, through the Air Coordinating Committee, Airspace Subcommittee, and are adopted when indicated in order to promote safety of the flying public. Compliance with the notice, procedures, and effective date provisions of section 4 of the Administrative Procedure Act would be impracticable and contrary to public interest, and therefore is not required. Part 601 is amended as follows:

1. Section 601.1075 *Control area extension, Baltimore, Md.,* is revoked.

2. Section 601.1129 is amended to read:

§ 601.1129 *Control area extension (Washington, D. C.).* All that area within a 40 mile radius of the Washington National Airport, excluding that portion northeast of the airport bounded on the west by the eastern boundary of Red civil airways Nos. 29 and 45 and on the south by the northern boundary of Green civil airway No. 5 and excluding the Washington Airspace Reservation and all danger areas.

3. Section 601.4013 *Green civil airway No. 3 (San Francisco, Calif., to New York, N. Y.)* is amended by adding the following compulsory reporting point after "Allentown, Pa., radio range station;": "the intersection of the east course of the Allentown, Pa., radio range and the southwest course of the Newark, N. J., radio range;"

4. Section 601.4223 *Red civil airway No. 23 (United States-Canadian Border to New York, N. Y.)* is amended by deleting compulsory reporting point "the intersection of the southwest course of the Poughkeepsie, N. Y., radio range and the northwest course of the New York (La Guardia), N. Y., radio range" and adding the following compulsory reporting point in lieu thereof: "the Paterson, N. J., non-directional radio beacon."

(Sec. 205, 52 Stat. 984, as amended; 49 U. S. C. 425. Interprets or applies sec. 601, 52 Stat. 1007, as amended; 49 U. S. C. 551)

This amendment shall become effective 0001 e. s. t. January 1, 1951.

[SEAL] DONALD W. NYROP,
Administrator of Civil Aeronautics.

[F. R. Doc. 50-12471; Filed, Dec. 29, 1950; 8:45 a. m.]

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Federal Security Agency

PART 141—TESTS AND METHODS OF ASSAY FOR ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

PART 146—CERTIFICATION OF BATCHES OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

RECAPITULATION AND REPUBLICATION OF REGULATIONS

The following is a recapitulation and republication of the regulations contained in Parts 141 and 146. This recapitulation includes all amendments through December 12, 1950 (15 F. R. 8965). It contains no new material.

[SEAL] OSCAR R. EWING,
Administrator.

PART 141—TESTS AND METHODS OF ASSAY FOR ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

Sec.

AUTHORITY: §§ 141.1 to 141.406 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 141.1 *Sodium penicillin, calcium penicillin, potassium penicillin; potency*—(a) *Cylinders (cups).* Use stainless steel cylinders with an outside diameter of 8 mm. (±0.1 mm.), an inside diameter of 6 mm. (±0.1 mm.), and a length of 10 mm. (±0.1 mm.).

(b) *Culture media.* Use ingredients that conform to the standards prescribed by the U. S. P. or N. F. (1) Make nutrient agar for the seed layer and for carrying the test organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Glucose	1.0 gm.
Agar	15.0 gm.
Distilled water, q. s.	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(2) Make nutrient agar for the base layer as follows:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Agar	15.0 gm.
Distilled water, q. s.	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(3) Make nutrient broth, for preparing an inoculum of the test organism, as follows:

Peptone	5.0 gm.
Yeast extract	1.5 gm.
Beef extract	1.5 gm.
Sodium chloride	3.5 gm.
Glucose	1.0 gm.
Dipotassium phosphate	3.68 gm.
Potassium dihydrogen phosphate	1.32 gm.
Distilled water, q. s.	1,000.0 ml.

pH 7.0 after sterilization.

In lieu of preparing the media from the individual ingredients specified in paragraphs (b) (1), (2), and (3) of this section, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modification of the individual ingredients specified in paragraphs (b) (1), (2), and (3) of this section are permissible if the resulting media possess growth promoting properties at least equal to the media described.

(c) *Working standard.* Keep the working standard (obtained from the Food and Drug Administration) at room temperature in tightly stoppered vials, which in turn are kept in larger stoppered tubes containing a suitable desiccant. Weigh out carefully in an atmosphere of 50 percent relative humidity or less between 4 and 5 mg. of the working standard and dilute with sterile 1 percent phosphate buffer (pH 6.0) to make a stock solution of any convenient concentration. Keep this solution at a temperature of about 10° C., and use for one day only. From this stock solution make appropriate working dilutions.

(d) *Preparation of sample.* Dissolve aseptically, in sterile distilled water, the sample to be tested to make an appropriate stock solution.

(e) *Preparation of plates.* Add 21 ml. of agar to each Petri dish (20 x 100 mm.). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. The test organism is Staphylococcus aureus (F. D. A. 209-P or 9144) American Type Culture Collection. Maintain the test organism on agar slants and transfer to a fresh agar slant about once a week. Prepare an inoculum for the plates by transferring the culture from the agar slant into broth and incubate at 32° C.–35° C. From 16 to 24 hours thereafter add 2.0 ml. of this broth culture to each 100 ml. of agar which has been melted and cooled to 48° C. Mix the culture and agar thoroughly and add 4 ml. to each of the plates containing the 21 ml. of the uninoculated agar. Tilt the plates back

and forth to spread the inoculated agar evenly over the surface. Porcelain covers glazed on the outside are used. Place four cylinders on the agar surface so that they are at approximately 90° intervals on a 2.8 cm. radius. In so placing the cylinders drop them from a height of ½ inch, using a mechanical guide or device. A suspension of the test organism may be used in place of the broth culture described above in preparing the inoculum for the seeding of plates. Prepare such suspension as follows: Wash the organisms from an agar slant which has been incubated for 24 hours at 32° C.–35° C. and stored for 24 hours at room temperature with 2.0 ml. of sterile physiological saline onto a large agar surface such as that provided by a Roux bottle containing 300 ml. of agar. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate 24 hours at 32° C.–35° C. and store for 24 hours at room temperature. Wash the resulting growth from the agar surface with about 50 ml. of sterile physiological saline. Standardize this suspension by determining the dilution which will permit 20 percent light transmission through a filter at 6500 Angstrom units in a photoelectric colorimeter. Add 1.5 to 2.0 ml. of this resulting dilution to each 100 ml. of agar which has been melted and cooled to 48° C. to prepare the inoculum for the plates. The suspension may be used for one week.

(f) *Assay.* Use four plates for each sample. Fill one cylinder on each plate with a 1.0 unit per ml. dilution, and one with a 0.25 unit per ml. dilution, of the working standard. Add the estimated dilutions of 1.0 unit per ml. and 0.25 unit per ml. of the sample under test to the remaining two cylinders on each plate. Carefully place the plates in racks and incubate 16 to 18 hours at 32° C.–35° C. After incubation measure the diameter of each circle of inhibition to the nearest 0.5 mm. using a colony counter with a mm. scale etched into the supporting glass over the light source. Other measuring devices of equal accuracy may be used.

(g) *Estimation of potency and error.* (1) Use the accompanying chart (Chart 1) and nomograph (Chart 2) for estimating the potency and its error. To use the chart for estimating potency two values, namely, V and W, are required. For each plate calculate two values

$$v=(u_L+u_H)-(s_L+s_H)$$

and

$$w=(u_H+s_H)-(u_L+s_L)$$

where s_H and s_L are the diameters of the zones of inhibition in mm. of the 1.0 unit and 0.25 unit dilutions of the standard, respectively, and u_H and u_L refer similarly to the corresponding dilutions of the sample under test. The value V is the sum of the v values for all plates and W is the sum of the w values for all plates. To estimate the potency locate the point on the chart corresponding to the values of V and W, and the potency can be read from the radial lines on the chart.

(2) The error of the assay is estimated by using the nomograph which requires five values, namely, the potency, V, W, Rv, and Rw. Rv (the range of the v's) is the highest value of v minus the lowest value of v obtained from the individual plates. Similarly, Rw is the difference between the highest and lowest w values. After obtaining these five values, connect with a straightedge the points corresponding to v and w on the respective scales on the right side of the nomograph. Mark with a pin or sharp-pointed pencil the intersection of the straightedge and the diagonal line of the nomograph. Move the straightedge so that it connects the value of Rw on its scale and the diagonal line at the point of the pin. The value for Q is thus determined by the scale value where the straightedge crosses the line labeled "Q". T is obtained by adding the squares of Q and Rv. On the left side of the chart connect the values of T and W with the straightedge and read the value of the ratio (error of assay-potency) where the straightedge intersects the scale of values for the ratio. This value multiplied by the potency equals the percentage error of the assay. The error of the assay calculated here estimates only how closely one assayist can check himself on any given set of dilutions of unknown and standard. It does not include any errors of weighing or errors due to variations in materials or subdivisions of a lot of penicillin.

The chart for determining potency should not be used for determinations of potency lower than 50 percent or higher than 150 percent of the standard. If the potency lies outside these limits, the assay should be repeated using a higher or lower dilution. The radial lines on the chart beyond these limits permit a rough estimation of potency from as low as 5 percent to as high as 1,000 percent when low values of W are found. If the value of V or W falls outside the limits of the chart, divide both V and W by the same proper number to bring them into the range of the chart and read the potency from the radial lines as before. If 11.4 Rw is greater than W, the slope of the assay does not differ significantly from zero and the assay is invalid. (The figure 11.4 was obtained by use of Student's "t" test for determining the significance of a slope.)

In certain laboratories it has been noted that with the 4 to 1 ratio, involving concentrations of 0.25 unit for the low dose, the zone of inhibition given by this dose may either be too small for accurate reading or have edges which are poorly defined. In order to permit the use of a higher concentration of penicillin for the low dose the third of the attached charts (Chart 3) may be used in assays in which the ratio of doses is 2 to 1, i. e., the high dose (sH) is twice the low dose (sL). As in the preceding chart (Chart 1), if the potency lies outside the limits of 50 percent to 150 percent the assay should be repeated, using a lower or higher dilution. The potencies beyond these limits are to be used for rough estimation purposes only. These extensions can also be used for four (or more) plate assays if both V and W are divided by the same proper number to bring them into the range of the chart. The error of the assay using the ratio of doses 2 to 1 is estimated by using the nomograph (Chart 2) in the same manner as described for the 4 to 1 ratio of doses. However, the resultant error of the assay derived in this manner must be divided by 2 to give the correct error of the assay for the 2 to 1 ratio of doses.

(h) *Standard curve technique.* The potency of a sample may also be determined by the standard curve technique using a single dose of standard and unknown.

Dilute the sample to be tested to 1.0 unit per ml. (estimated) in 1 percent phosphate buffer pH 6.0. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8 cm. radius. Use three plates for each sample. Fill 3 cylinders on each plate with the 1.0 unit/ml. standard and 3 cylinders with the 1.0 unit/ml. (estimated) sample, alternating standard and sample. Incubate the plates for 16 to 18 hours at 32° C.–35° C. and measure the diameter of each circle of inhibition. At the same time prepare a standard curve using concentrations of the standard of 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, and 1.5 units/ml. in sterile 1 percent phosphate buffer pH 6.0. Use three plates for the determination of each point on the curve, a total of 27 plates. On each of three plates fill 3 cylinders with the 1.0 unit/ml. standard and the other 3 cylinders with the concentration under test. Thus there will be 81 one-unit determinations and 9 determinations for each of the other points on the curve. After the plates have incubated read the diameters of the circles of inhibition. Average the readings of 1.0 unit/ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings of the 1.0 unit/ml. concentration. The average of the 81 readings of the 1.0 unit/ml. concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 unit/ml. reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8 unit concentration, the average of the 81 readings of the 1.0 unit concentration is 20.0 mm., and the average of the 1.0 unit concentration of this set of 3 plates is 19.8 mm., the correction is 0.2 mm. If the average reading of the 0.8 unit concentration of these same 3 plates is 19.0 mm. the corrected value is then 19.2 mm. Plot these corrected values including the average of the 1.0 unit/ml. concentration on 2-cycle semilog paper using the concentration in units per ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. The 10 points selected to determine the curve are arbitrary and should be so chosen that the limits of the curve will fill the needs of the laboratory. However, the potency of the sample under test should fall in the interval of from 60 percent to 150 percent of the correction point of the standard curve.

To estimate the potency of the sample average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 1.0 unit zone

on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 unit value on the curve. From the curve read the potencies corresponding to these corrected values of zone sizes.

(i) *Potency.* The potency of sodium penicillin, calcium penicillin, and potassium penicillin is satisfactory when assayed by the methods described in this section if the immediate containers are represented to contain:

(1) 200,000 units or less and contain 85 percent or more of the number of units so represented;

(2) More than 200,000 units and contain 90 percent or more of the units so represented.

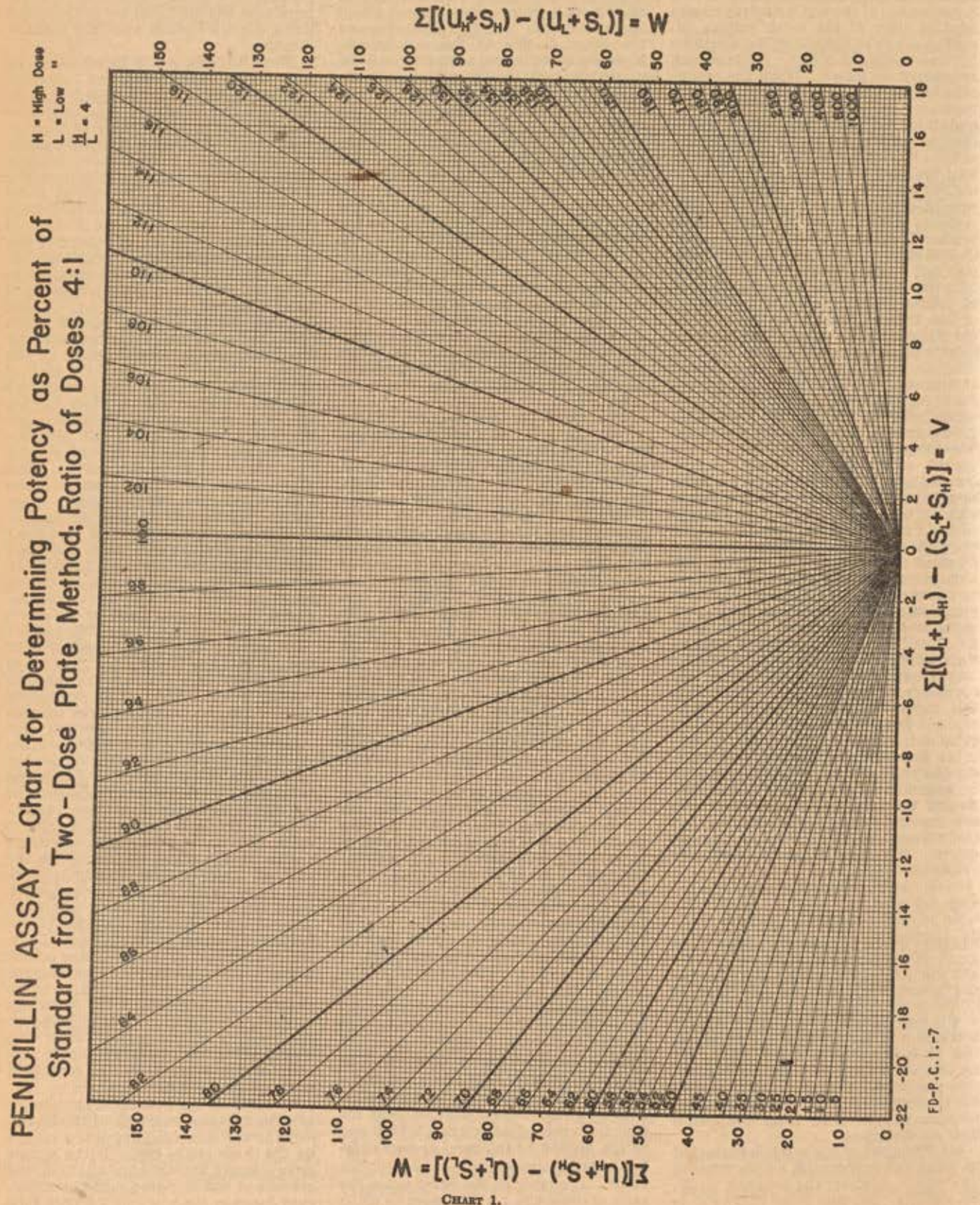

CHART 1.

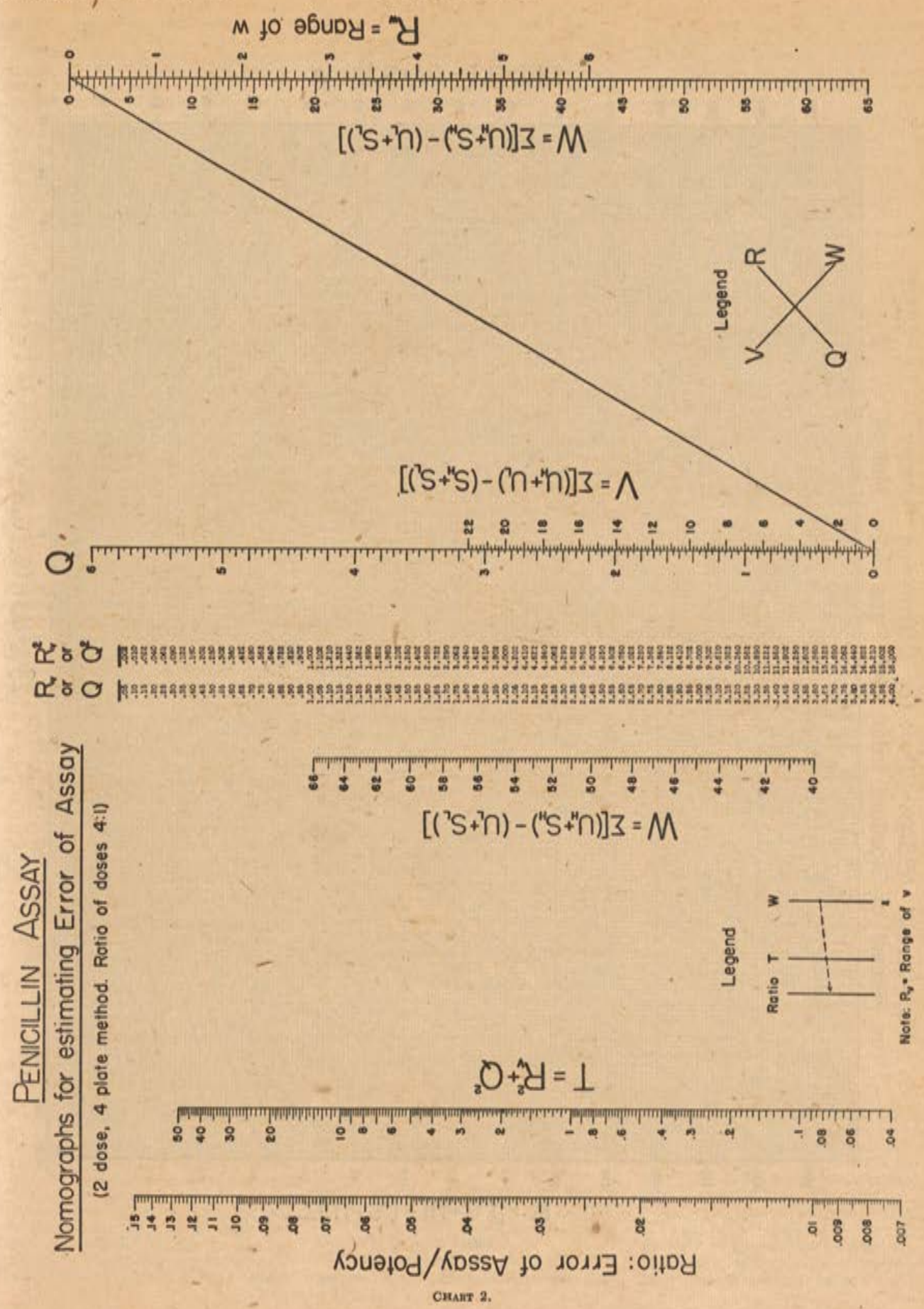
PENICILLIN ASSAY
Nomographs for estimating Error of Assay
(2 dose, 4 plate method. Ratio of doses 4:1)
Ratio: Error of Assay/Potency
T = R² + Q²
Legend
Ratio T W
Note: R_W = Range of w
W = Σ[(U_u+S_u) - (U_l+S_l)]
V = Σ[(U_u+U_l) - (S_u+S_l)]
Q
R² or Q²
R or Q
Legend
R W
V Q
W = Σ[(U_u+S_u) - (U_l+S_l)]
R_W = Range of w

CHART 2.

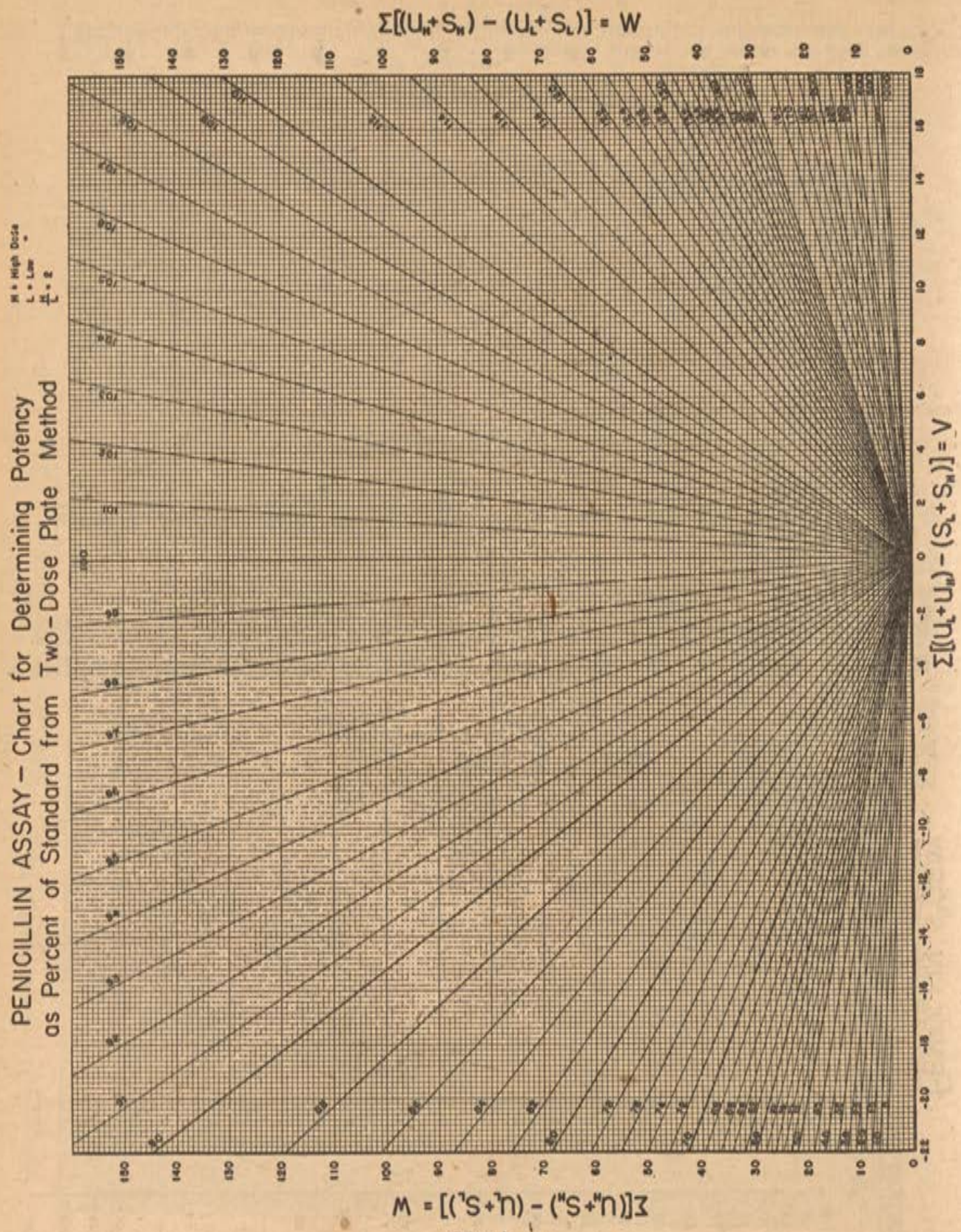
PENICILLIN ASSAY – Chart for Determining Potency as Percent of Standard from Two-Dose Plate Method
H = High Dose
L = Low
Σ[(U_H+S_H) – (U_L+S_L)] = W
Σ[(U_H+U_L) – (S_L+S_H)] = V
Σ[(U_H+S_H) – (U_L+S_L)] = W

CHART 3.

§ 141.2 *Sodium penicillin, calcium penicillin, potassium penicillin; sterility*—(a) *Culture medium.* Use U. S. P. fluid thioglycolate medium I or a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium and has growth-promoting, buffering, and oxygen-tension-controlling properties equal to or better than those of such medium.

In the preparation of the medium, from either the individual ingredients or any dehydrated mixture, avoid contamination with calcium.

(b) *Conduct of test.* Dissolve the sample to be tested in sterile distilled water so that each milliliter contains not less than 10,000 and not more than 40,000 units. Transfer aseptically 1.0 ml. to each of four tubes containing 15 ml. of thioglycolate medium, to which has been added sufficient penicillinase to inactivate at least 50,000 units of penicillin. Let stand at room temperature for not less than 2 hours, shaking the tubes at ½-hour intervals. Inoculate one of these tubes with 1.0 ml. of 1:1000 dilution of an 18–24-hour broth culture of M. pyogenes var. aureus (P. C. I.-209P and American Type Culture Collection 6538P) and incubate all four tubes for 4 days at 32° C.–35° C. The inoculated tube should show growth at the end of 4 days; if so, and no other tube shows growth, the sample is sterile.

§ 141.3 *Sodium penicillin, calcium penicillin, potassium penicillin; pyrogens*—(a) *Test animal.* Use healthy rabbits, weighing 1,500 gm. or more, which have been maintained for at least 1 week on a uniform, unrestricted diet and have not lost weight during this period. For subsequent tests, animals utilized for previous tests may be used after a rest period of not less than 2 days. Use a clinical rectal thermometer after it has been tested in a rabbit to determine the time required to reach maximum temperature. (Other recording devices of equal sensitivity are acceptable.) Insert the thermometer or other recording device beyond the internal sphincter and allow it to remain a sufficient time to reach maximum temperature as determined above. Make four rectal temperature readings on each of the animals to be used in the test at 2-hour intervals, 1 to 3 days before such use (this may be omitted for any animal that has been used in such tests during a preceding period of 2 weeks). House the test animals in individual cages and protect them from disturbances likely to cause excitement. Exercise particular care to avoid exciting the animals on the day of taking the control temperatures and on the test day. Maintain the animals in an environment of uniform temperature (±5° F.) at all times.

(b) *Conduct of test.* Heat all syringes and needles to be used in a muffle furnace at 250° C. for not less than 30 minutes to render them pyrogen-free and sterile. Perform the test in a room held at the same temperature as that in which the animals are housed. During the test restrain the animals in individual stocks. Withhold all food from 1 hour before the first temperature reading until after the final reading of the day. Take a control temperature reading not more than 15 minutes after the animal is removed from the cage. Use three animals for each test, but do not use those with control temperatures of 38.8° C. or under and 39.9° C. or over. Dilute the sample with pyrogen-free, sterile, distilled water to a concentration of 2,000 units per ml. and warm to approximately 37° C. Inject 2,000 units (estimated) per kg. of rabbit intravenously through an ear vein within 15 minutes subsequent to the control temperature reading. Read temperatures 1 hour after injection and each hour thereafter until three readings have been made. The sample is non-pyrogenic if when so tested no animal shows a rise in any of the temperature readings, after injection, of 0.6° C. or more above the control temperature of such animal. If only one animal shows such a rise in temperature, or if the sum of the temperature rises of the three animals exceeds 1.4° C., repeat the test on five additional animals. The sample is nonpyrogenic if not more than one of these five animals shows a rise in temperature of 0.6° C. or more above the control temperature of such animal.

§ 141.4 *Sodium penicillin, calcium penicillin, potassium penicillin; toxicity.* Inject intravenously each of five mice, within the weight range of 18 to 25 grams, with 0.5 ml. of a solution of the sample prepared by diluting with sterile distilled water to approximately 4,000 units per ml. The injection should be made over a period of not more than 5 seconds. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with five unused mice weighing 20 grams (±0.5 gm.) each; if all animals survive the repeat test, the sample is nontoxic.

§ 141.5 *Sodium penicillin, calcium penicillin, potassium penicillin*—(a) *Moisture.* In an atmosphere of about 10 percent relative humidity, transfer 30 to 50 mg. of the finely powdered sample to a tared weighing bottle or weighing tube equipped with a capillary-tube stopper, the capillary having an inside diameter of 0.20 to 0.25 mm. Weigh the bottle or tube and place it in a vacuum oven, without removing the stopper and dry at a temperature of 60° C. and a pressure of 5 mm. of mercury or less for 3 hours. At the end of the drying period, fill the vacuum oven with air dried by bubbling it through sulfuric acid; place weighing bottles or tubes in a desiccator over phosphorous pentoxide, allow to cool to room temperature, and reweigh. Divide the loss in weight by the weight of the sample and multiply by 100 to obtain the percentage of moisture.

(b) *pH.* Dilute the sample to be tested with carbon-dioxide-free distilled water so that the resulting solution contains 5,000 to 10,000 units per ml. Determine the pH of this solution at 25° C. using a pH meter equipped with a glass and a calomel electrode.

(c) *Microscopical test for crystallinity of sodium penicillin and potassium penicillin.* Mount in mineral oil and examine by means of a polarizing microscope. Crystalline penicillin shows resolvable particles which reveal the phenomena of birefringence (interference colors) and extinction positions on revolving the microscope stage. Crystalline penicillin also reveals diagnostic refractive indices when examined by the immersion method.

(d) *Heat stability*—(1) *Crystalline penicillin, crystalline penicillin G.* Store a weighed sample (approximately 30 mg.) of crystalline penicillin in an unstoppered 50-ml. Erlenmeyer flask for 4 days in an electric oven at 100° C., ± 1°. At the end of this period it does not show a loss of more than 10 percent of its original potency when determined as follows: Dilute a weighed sample (approximately 30 mg.) with 1 percent phosphate buffer at pH 6.0 to a concentration of approximately 1.2 mg./ml. (2,000 units/ml.). Add 2.0 ml. aliquots to each of two 125-ml. glass-stoppered Erlenmeyer or iodine flasks. To one add 2.0 ml. of 1N NaOH and allow to stand at room temperature for 15 minutes. At the end of this time add 2.0 ml. of 1.2N HCl and add 10.0 ml. of 0.01N I_2 (prepared from 0.1N I_2 U. S. P.) (Equal volume of 1N NaOH and 1.2N HCl when mixed give pH 1.0.) After 15 minutes titrate the excess iodine using 0.1N $Na_2S_2O_3$ (prepared from 0.1N $Na_2S_2O_3$) standardized accurately against potassium iodate. Toward the end of the titration add approximately 5 ml. of CCl_4. Continue the titration by the addition of 0.01 to 0.02 ml. portions of the 0.01N $Na_2S_2O_3$ shaking vigorously after each addition. The end-point is reached when the CCl_4 layer becomes colorless. To the second flask add 10 ml. of the 0.01N I_2 and titrate immediately with 0.01N $Na_2S_2O_3$ for the blank determination. Regard the difference in titers divided by 2.52 as the milligrams of penicillin sodium salt.

$$\text{Percent loss of potency} = \frac{\text{Original assay} - \text{Assay after 4 days at 100° C.} \times 100}{\text{Original assay}}$$

(2) *Crystalline penicillin O.* Store a weighed sample (approximately 30 mg.) of crystalline penicillin O in an unstoppered 50-ml. Erlenmeyer flask for 4 days in an electric oven at 100° C.,±1°. At the end of this period it does not show a loss of more than 10% of its original potency when determined by the method described in § 141.1.

(e) *Crystalline penicillin G*—(1) *Reagents.* The reagents described in subdivisions (i), (ii), and (iii) of this subparagraph are freshly prepared every three days and are of such quality that when used in this procedure with a known penicillin G not less than 97 percent of penicillin G is recovered.

(i) *Amyl acetate solution.* Saturate the amyl acetate with the N-ethyl piperidine salt of penicillin G by adding 2 mg. of the salt for each 1 ml. of the solvent. Cool this solution to 0° to 8° C. and filter

by drawing it through a plug of cotton on the tip of a pipette immediately before use.

(ii) *Acetone solution.* Saturate reagent grade acetone with the N-ethyl piperidine salt of penicillin G using 3 mg. of salt for each 1 ml. of acetone. Cool this solution to 0° to 8° C. and filter by drawing it through a plug of cotton on the tip of a pipette immediately before use.

(iii) *N-ethyl piperidine solution.* N-ethyl piperidine should be stored in brown bottles in a refrigerator. Dilute 1.0 ml. of this reagent with 4.0 ml. of amyl acetate. Saturate this solution with the N-ethyl piperidine salt of penicillin G using about 3 mg. of the salt for each 1.0 ml. of solution. Cool this solution to 0° to 8° C. and filter by drawing it through a plug of cotton on the tip of a pipette immediately before use.

(iv) *Phosphoric acid solution.* Prepare by dissolving 1.0 ml. of reagent grade phosphoric acid (85 percent) in 4.0 ml. of water. Cool to 0° to 8° C. and shake before using.

(v) *Sodium sulfate.* Use powdered anhydrous reagent grade sodium sulfate.

(2) *Procedure.* Accurately weigh from 60 to 70 mg. of the sample to be tested in a glass test tube or glass vial of approximately 10 ml. capacity. Add 2.0 ml. of water to dissolve the penicillin and cool the solution to 0° to 5° C. Add 2 ml. of the amyl acetate solution and 0.5 ml. of the phosphoric acid solution, stopper and shake vigorously for approximately 15 seconds. Centrifuge to obtain a clear separation of the two layers (approximately 20 seconds). After centrifuging remove as much of the amyl acetate layer as possible (usually about 1.7 to 1.8 ml.) with a 2 ml. hypodermic syringe equipped with a suitable needle. Place about 0.1 gm. of the sodium sulfate in a micro filter funnel (approximately 10 mm. diameter) having a fritted glass disc of medium porosity and add the amyl acetate solution from the hypodermic syringe. Collect the filtrate by suction in a small test tube placed in a suction flask, which is surrounded by cracked ice. Pipette a 1.0 ml. aliquot of the amyl acetate filtrate into a tared flat bottom glass tube (approximately 15 x 50 mm.) containing 1.0 ml. of the acetone solution and 0.5 ml. of the N-ethyl piperidine solution. The time elapsing between acidification and the addition of the filtrate to the above reagents should not be more than three minutes. Place the glass tube containing this mixture in a large weighing bottle, stopper the bottle and allow to stand for not less than 2 hours in a refrigerator at 0° to 8° C. Remove the liquid from the precipitate by means of a tared micro filter stick and wash with a total of 1 ml. of the acetone solution adding the latter by means of a hypodermic syringe equipped with a fine needle. Place the filter stick inside the glass tube, dry under vacuum at room temperature for not less than 1 hour, and weigh. (Save all N-ethyl piperidine penicillin G residues for saturating reagents.)

$$\text{Percent of sodium penicillin G} = \frac{\text{mg. N-ethyl piperidine penicillin precipitate} \times 159.3}{\text{Weight of sample mg.}}$$

$$\text{Percent of potassium penicillin G} = \frac{\text{mg. N-ethyl piperidine penicillin precipitate} \times 166.5}{\text{Weight of sample mg.}}$$

(f) *Penicillin K content.* Determine the content of penicillin K by the following method:

Dilute a weighed sample or the contents of a vial with 0.3 M phosphate (Na_2HPO_4 and KH_2PO_4) buffer pH 6.0 to give a solution containing approximately 1,000 units/ml. In the case of calcium penicillin where a precipitate of calcium phosphate occurs, remove the precipitate by filtration and use the clear filtrate. Place a 15.0 ml. aliquot of this solution in a 125 ml. separatory funnel, add 30.0 ml. of chloroform U. S. P. and shake for 1 minute. (Carry out all operations at room temperature.) Allow the mixture to stand with occasional swirling to settle the droplets of chloroform until the top layer is clear (usually about 10 minutes). Draw off all but about 2 ml. of the lower chloroform layer through a small pledget of cotton into a glass-stoppered flask. Take a 4.0 ml. aliquot of the original solution, a 4.0 ml. aliquot of the buffer solution remaining in the separatory funnel and a 10.0 ml. aliquot of the chloroform solution and determine the mg./ml. of penicillin in each by the iodometric assay procedure described in paragraph (d) of this section using 4.0 ml. of the 1N NaOH and 4.0 ml. of the 1.2N HCl for each of the above aliquots. Make blank determinations on the same size aliquots. Calculate the percent penicillin in the buffer layer and in the chloroform layer as compared to the original solution. The sum of these percentages should be 100% ±2%. The percent penicillin K= (96.92+% in chloroform−% in buffer) ×1.67. (The factors in the above formula are based on distribution coefficients of penicillin K and G between chloroform and aqueous phosphate buffer at pH 6.0.)

(g) *Penicillin G content of crystalline penicillin O*—(1) *Reagents.* (i) Concentrated sulfuric acid (sp. gr. 1.84).

(ii) Fuming nitric acid (sp. gr. 1.5).

(iii) Ammonium hydroxide (sp. gr. 0.90).

(iv) Solution of hydroxylamine hydrochloride. (Prepare by dissolving 15 gm. of reagent grade hydroxylamine hydrochloride in sufficient water to make 100 ml. of solution. Prepare a fresh solution once a week.)

(2) *Procedure.* Accurately weigh 75–85 mg. of penicillin O into a 50-ml. Erlenmeyer flask and add 2.0 ml. of concentrated sulfuric acid. When the sample is completely dissolved, add 0.4 ml. of fuming nitric acid and quickly swirl the flask to mix the contents thoroughly. Heat the flask on a steam bath for 40 minutes; cool for several minutes in an ice bath and add 10.0 ml. of cold water rapidly. When the solution has reached room temperature, pipette 5.0-ml. aliquots into each of two 50-ml. Erlenmeyer flasks. To one of the flasks add 2.0 ml. water (the blank). To the other flask add 2.0 ml. of the hydroxylamine hydrochloride solution. Cool both flasks in an ice bath, and while still in the ice bath make alkaline by adding 5.0 ml. of ammonium hydroxide, dropwise from a burette. Allow to stand for 45 minutes at room temperature and obtain a density reading of the color in a suitable photoelectric colorimeter, using a 550 mμ filter and a 1-cm. cell. Use the blank determination to set the instrument at the zero point. Determine the percent penicillin G from a standard curve prepared as follows: Add known increments of the penicillin G working standard (0.1 mg. to 1.5 mg.) to 75.0-mg. portions of the penicillin O working standard (obtained from the Food and Drug Administration). Determine the density readings by the method described above, except that in lieu of the water blank use the color developed with a 75.0-mg. portion of the penicillin O working standard to set the instrument at the zero point. This automatically corrects for any penicillin G present in the penicillin O working standard. Plot the density readings obtained against the penicillin G concentrations and use as the standard curve.

(h) *Penicillin O content.* Determine by means of a suitable infrared spectrometer, using the following procedure: Grind the sample to a uniform powder using a mortar and pestle. Weigh by difference, 100–150 mg. of liquid petrolatum into an agate mortar. Divide the actual weight of the liquid petrolatum by three, and add exactly this amount of the powdered penicillin O to the liquid petrolatum in the mortar. Mix with a small spatula and then mull thoroughly with the pestle until a uniform consistency is obtained. Use two circular rock-salt plates, each 2 inches in diameter as the absorption cell. Place a small drop of the mull in the center of one of the rock-salt plates. Place a brass spacer, 0.0036 inch thick, on the plate. (This spacer is cut in the shape of a circular gasket with a 1-inch center hole and a slit to permit the escape of air when the two plates are pressed together.) Put on the top salt plate gently and slowly squeeze together to spread the mull uniformly. Clamp the two plates firmly together in a metal cell holder. (The cell holder consists of two metal plates, one containing a rectangular center slit ¼ inch wide x ⅝ inch long, the other with a center hole 1 inch in diameter. The two plates are clamped together by means of threaded studs and nuts.) Examine the assembled cell by holding it up to the light. It should appear smooth, free of any air bubbles, and not in contact with the spacer. Adjust the amplification of the spectrometer to full-scale deflection for one microvolt, set the slit opening to about 0.300 and run the spectrum from 9.4 to 10.7 microns, using an automatic slit-control mechanism and taking a zero reading (shutter closed) at the beginning and at the end of the run. Draw a base line between two points, one on each side of the analytical band (10.1 microns)

and calculate the base-line optical density, using the following formula:

$$D_B = \log\ 10 \frac{I_B}{I_p}$$

where:

D_B = base-line optical density.
I_p = distance from the zero line to the maximum absorption of the band.
I_B = distance from the zero line to the base line, measured at the same wave length as I_p.

Using known mixtures of penicillin G working standard and penicillin O working standard, prepare a standard curve by plotting the base-line optical densities obtained against the percent penicillin O. Obtain the percent penicillin O in the sample under test from this standard curve.

§ 141.6 *Sodium penicillin, calcium penicillin, potassium penicillin; penicillin X.* Dissolve the contents of a 100,000 unit ampul in about 20 ml. of ice cold distilled water. Transfer quantitatively to a 100 ml. volumetric flask, rinsing the ampul with small portions of ice cold water and make to 100 ml. Pipette a 50.0 ml. aliquot into a 125 ml. separatory funnel, then add 50.0 ml. of cold chloroform and shake the mixture. Add an amount of approximately 1N H_2SO_4 to bring the pH of the aqueous layer to 2.0. (The amount of 1N H_2SO_4 to be added is calculated by titrating a separate 5.0 ml. aliquot of the 100 ml. dilution to pH 2.0 using a suitable pH meter.) Shake the mixture vigorously for one minute. Allow the layers to separate and filter the chloroform through a small pledget of cotton, moistened with chloroform, into a second 125 ml. separatory funnel. Shake the acid aqueous solution with a second 50.0 ml. of cold chloroform and, when the layers have separated, withdraw the chloroform through the same filter into the second separatory funnel. Immediately neutralize the acid aqueous solution, containing the penicillin X, with 0.1N NaOH to pH 6.5 to 7.0 using the pH meter and make to 100 ml. with water. Make appropriate dilutions in 1 percent phosphate buffer at pH 6.0 and assay as directed in § 141.1 (f) or (h). Shake the combined chloroform extracts, containing any penicillin G, etc., with small successive portions of cold $NaHCO_3$ solution (0.1 percent), until the combined $NaHCO_3$ extracts give a pH of 7.0, and make to 100 ml. with water. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. Assay these last dilutions as directed in § 141.1 (f) or (h). The potency of the penicillin X fraction plus potency of the penicillin G, etc., fraction should approximate that of the potency of the original solution. All of the above extractions should be carried out in a cold room.

§ 141.7 *Penicillin in oil and wax*—(a) *Potency.* Proceed as directed in § 141.1 except paragraph (f) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample as follows:

Liquefy the sample by warming, thoroughly mix, and withdraw 1.0 ml. using a sterile syringe equipped with an 18-gauge needle. Transfer to a separatory funnel containing approximately 50 ml. of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 25-ml. portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-ml. quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared by transferring aseptically 1.0 ml. of the penicillin in oil and wax to a blending jar containing 100 ml. of 1 percent phosphate buffer at pH 6.0. Using a high-speed blender, blend this mixture for 1 minute and then make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. If the label represents the potency of the penicillin in oil and wax as 200,000 units per milliliter or less, it is satisfactory if it is 85 percent or more of the potency so represented; if represented as more than 200,000 units per milliliter, it is satisfactory if it is 90 percent or more of the potency so represented.

(b) *Sterility.* Add aseptically approximately 1.0 milliliter of the sample to 9.0 milliliters of sterile cottonseed oil. Shake vigorously. Transfer 1.0 milliliter aseptically to each of four tubes containing 15 milliliters of fluid thioglycolate medium, to which has been added sufficient penicillinase to inactivate the penicillin present, and proceed as directed in § 141.2.

(c) *Moisture*—(1) *Reagents*—(i) *Karl Fischer reagent.* Preserve the reagent in glass-stoppered bottles and use from an all glass automatic burette, protecting the solution from the moisture in the air.

(ii) *Water-methanol solution.* Use methanol containing approximately 1 mg. of water per milliliter. Store the solution in a glass bottle attached to an automatic burette and protect from moisture in the air at all times.

(2) *Standardization of Karl Fischer reagent.* Add a known volume of the Karl Fischer reagent to a suitable titrating vessel which has been previously dried at 105° C. and cooled in a desiccator. Introduce a mechanical stirrer and two platinum electrodes which are connected to a suitable electrometric apparatus for measurement of the endpoint. Start the stirrer and titrate with the water-methanol solution until the endpoint is reached. Calculate the milliliters of Karl Fischer reagent equivalent to each milliliter of water-methanol.

Add an accurately weighed quantity of water (approximately 50 mg.) to a dry titrating vessel, add an excess of the Karl Fischer reagent and back titrate with the water-methanol solution as above. Calculate the milligrams of water equivalent to each milliliter of the Karl Fischer reagent. Standardize the Karl Fischer reagent in this manner daily.

$$e = \frac{w}{v_1 - v_2 f}$$

where

e = milligrams of water equivalent to 1 ml. Karl Fischer reagent.
w = weight of water in milligrams.
v_1 = volume of Karl Fischer reagent used.
v_2 = volume of methanol used.
f = volume ratio of Karl Fischer reagent to water-methanol solution.

(3) *Procedure.* Transfer 1.0 ml. of the penicillin in oil and wax to a dry titrating vessel, add 10 ml. of dry chloroform and an excess of the Karl Fischer reagent and back titrate with the water-methanol solution until the endpoint is reached. Transfer 10 ml. of the dry chloroform used to a dry titrating vessel, add an excess of Karl Fischer reagent, and titrate with the water-methanol as above. Calculate the milliliters of Karl Fischer reagent equivalent to 10 ml. of chloroform.

$$\text{Percent moisture} = \frac{(v_1 - v_2 f - b) \times e \times 100}{s \times 1000}$$

where

b = milliliters Karl Fischer reagent equivalent to 10 ml. of chloroform
s = volume of the sample in milliliters.

(d) *Measurement of penicillin particle size.* Vigorously shake the container to obtain an even suspension of the penicillin particles and immediately withdraw therefrom approximately 0.5 ml of the drug into a clean, dry, tuberculin syringe using a dry 18 gauge needle. Discard approximately the first 5 drops of the mixture extruded from the needle and then extrude approximately 1 minim of the remaining mixture into a test tube containing 3 to 4 ml. of light mineral oil. Thoroughly mix the contents of the tube and by means of a bacteriological loop (2 mm. inside diameter, 22 gauge wire), immediately place one loopful of the suspension on each ruled chamber of a bright line hemocytometer. (It is not necessary to use a cover slip.) Confirm by means of the low power objective of the microscope the even distribution of particles over the ruled areas of both chambers and repeat with another loopful of the suspension if even dispersion is not obtained.

Use a magnification of 430 or 440 diameters and a calibrated ocular micrometer to measure the penicillin particles. For the purpose of measurement and calculation, the predominant type of crystals observed shall be considered to represent the type of crystals present and the thickness and density of all particles shall be considered constant. Center a large penicillin particle in the microscopic field; measure the particle and all other particles in the field and repeat this operation on other fields until at least 200 particles are measured. Particles of less than 5 microns in length are disregarded. The grouping of the particles by length, the midpoint, the ratio of the midpoints, and the square of the ratio of the midpoints for each group are tabulated below:

Group	Length in microns	Midpoint	Ratio of midpoints	(Ratio)²
1	5-14	9.5	1.00	1.00
2	15-29	22.0	2.31	5.34
3	30-49	39.5	4.16	17.31
4	50-69	59.5	6.26	39.19
5	70-99	84.5	8.89	79.03
6	100-149	124.5	13.10	171.61
7	150-199	174.5	18.36	337.09
8	200-249	224.5	23.63	558.38
9	250-300	275.0	28.95	838.10

Calculate the percent particles in each group from the total number measured.

Determine the percent relative weight for each group as follows:

Plate type particles. Relative weight = (ratio)^2 × % of total particles in group.

$$\%\ \text{relative weight} = \frac{\text{relative weight} \times 100}{\text{total relative weight}}$$

Rod shaped particles. In the case of rod shaped particles measure the width as well as the length.

Relative weight = ratio × average width × % of total particles in group

$$\%\ \text{relative weight} = \frac{\text{relative weight} \times 100}{\text{total relative weight}}$$

When examined by the method described in this section not less than 50 percent of the total relative weight of the penicillin in the drug consists of penicillin having a particle size of not less than 50 microns in length.

§ 141.8 *Penicillin ointment*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof, and, in lieu of the directions in paragraph (d) of § 141.1, prepare the sample as follows:

Accurately weigh the container and contents and place 0.5 to 1.0 gm. into a separatory funnel containing approximately 50 ml. of peroxide-free ether. Reweigh the container to obtain weight of ointment used in the test. Shake ointment and ether until homogeneous. Shake with a 25-ml. portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-ml. quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared by placing an accurately weighed sample consisting of 0.5 to 1.0 gm. of the ointment into a glass blending jar containing 100 ml. of 1 percent phosphate buffer at pH 6.0. Using a high-speed blender, blend the mixture for 2 minutes and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The potency of penicillin ointment is satisfactory if it contains not less than 85 percent of the number of units per gram it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.7 (c), using a weighed sample of 1.0 to 2.0 gm. dissolved in a mixture of 10 ml. of dry chloroform and 10 ml. of carbon tetrachloride, but in lieu of calculating the milliliters of Karl Fischer reagent equivalent to 10 ml. of chloroform, determine the milliliters of reagent equivalent to 20 ml. of the mixture of chloroform and carbon tetrachloride.

§ 141.9 *Penicillin tablets*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample as follows:

Place 12 tablets in a mortar and add approximately 20 ml. of 1 percent phosphate buffer at pH 6.0. Disintegrate the tablets by grinding with a pestle. Transfer with the aid of small portions of the buffer solution to a 500-ml. volumetric flask and make to 500 ml. by adding sufficient phosphate buffer. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared as follows: Place 12 tablets in a blending jar and add thereto approximately 200 ml. of a 500-ml. quantity of 1 percent phosphate buffer at pH 6.0. After blending for 1 minute with a high-speed blender add the remainder of the 500 ml. of buffer. Blend again for 1 minute and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The average potency of tablets buffered penicillin is satisfactory if it contains not less than 85 percent of the number of units per tablet it is represented to contain.

(b) *Moisture.* Proceed as described in § 141.5 (a).

§ 141.11 *Penicillin with aluminum hydroxide gel*—(a) *Sodium penicillin, calcium penicillin, potassium penicillin.* Proceed as directed in §§ 141.1, 141.2, 141.4, and 141.5 (a) and (b); if crystalline penicillin, § 141.5 (c), (d), and (f); and if crystalline penicillin G, § 141.5 (e).

(b) *Aluminum hydroxide gel.* Thoroughly shake the aluminum hydroxide gel and transfer aseptically 1.0 and 0.1-ml. portions in triplicate to sterile Petri dishes. Pour into each Petri dish 20 ml. of nutrient agar, described in § 141.1 (b) (1), which has been melted and cooled to 48° C. Thoroughly mix the aluminum hydroxide and melted agar. Allow the agar to solidify, invert the Petri dishes, and incubate for 48 hours at 32° C.–35° C. Count the number of colonies appearing on the plates and calculate therefrom the number of viable bacteria per ml. of the aluminum hydroxide gel.

§ 141.12 *Penicillin troches*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample as follows:

(1) If the troche does not contain a masticatory substance, proceed as directed in § 141.9 (a).

(2) If the troche contains paraffin as a masticatory substance, place five troches in a separatory funnel containing 75 ml. of n-hexane; shake until the troches are dissolved. Shake with a 25-ml. portion of 1% phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-ml. quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1% phosphate buffer at pH 6.0.

(3) If the troche contains gum as a masticatory substance, cut each of five troches into fine pieces and place in a glass blending jar containing 100 ml. of a 50% acetone-water solution. Using a high-speed blender, blend for 3 to 5 minutes. Add an additional 100 ml. of a 50% acetone-water solution to the blender and blend for an additional 3 to 5 minutes, and then make the proper estimated dilutions in 1% phosphate buffer at pH 6.0.

The average potency of the troche is satisfactory if it contains not less than 85% of the number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a), or if it contains a masticatory substance proceed as directed in § 141.7 (c), using 1.0 to 2.0 gm. dissolved in 10 ml. of dry chloroform.

§ 141.13 *Penicillin dental cones*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample using 5 cones as directed in § 141.9 (a). The average potency of the cone is satisfactory if it contains not less than 85 percent of the number of units per cone it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.14 *Penicillin with vasoconstrictor*—(a) *Penicillin used in the packaged combination*—(1) *Potency.* Unless it is penicillin tablets, proceed as directed in § 141.1. If it is penicillin tablets, proceed as directed in § 141.9 (a).

(2) *Toxicity, moisture, pH, crystallinity, heat stability, penicillin G content.* Proceed as directed in §§ 141.4 and 141.5.

(b) *Dry mixture of penicillin with vasoconstrictor; potency, moisture.* Proceed as directed in §§ 141.1 and 141.5 (a).

§ 141.15 *Penicillin for surface application*—(a) *Potency.* Proceed as directed in § 141.9 (a) using the contents of 12 immediate containers.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.16 *Tablets aluminum penicillin*—(a) *Potency.* Proceed as directed in § 141.9 (a), using citrate buffer at pH 6.3 for making working dilutions of the working standards and for the sample under test in lieu of phosphate buffer. The citrate buffer is of the following composition:

	Grams
Citric acid	52.9
Sodium hydroxide (pellets)	28.25
Sodium citrate	388.0

Make up to 4000 ml. with distilled water.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.17 *Penicillin sulfonamide powder*—(a) *Potency.* Proceed as directed in § 141.9 (a), except prepare the samples as follows: Accurately weigh 0.5 gm. from each of 12 immediate containers and dissolve in 100 ml. of distilled water. From this solution make the proper estimated dilutions in 1% phosphate buffer at pH 6.0.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

(c) *Sterility.* Proceed as directed in § 141.2 except that sufficient penicillinase is added to the thioglycolate medium to inactivate the penicillin added in the test and in lieu of the directions in the first three sentences of paragraph (b) of § 141.2 proceed as follows:

Suspend aseptically approximately one-fourth of the sample to be tested (about 0.5 gm.) into each of four tubes containing 15 ml. of fluid thioglycolate medium with added penicillinase.

§ 141.18 *Penicillin vaginal suppositories*—(a) *Potency.* Proceed as directed in § 141.1 except paragraph (i) thereof and in lieu of the directions in paragraph (d) of § 147.1 prepare sample as follows:

Place 5 suppositories in a separatory funnel containing 150 ml. of peroxide-free ether. Shake the separatory fun-

nel vigorously to bring about complete mixing of the material with the ether. Shake with a 25-ml. portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25 ml. quantities of buffer. Combine all extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared as follows: Place 5 suppositories in a glass blending jar containing 200 ml. of 1 percent phosphate buffer at pH 6.0. Using a high-speed blender blend for 3 minutes and make the proper estimated dilution in 1 percent phosphate buffer at pH 6.0. The average potency of the suppository is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.7 (c) using a weighed suppository dissolved in 10 ml. of dry chloroform and 2 ml. of methanol from the titrating burette. (Correct for the amount of moisture in the solvents used.)

§ 141.19 *Buffered crystalline penicillin.* Proceed as directed in §§ 141.1, 141.2, 141.3, 141.4, 141.5 and 141.6.

§ 141.20 *Capsules buffered penicillin with pectin hydrolysate*—(a) *Potency.* Proceed as directed in § 141.1 except paragraph (i) thereof and in lieu of the directions in paragraph (d) of § 141.1 prepare samples as follows:

Place the contents of 12 capsules and the empty capsules into a 500 ml. volumetric flask. Add approximately 200 ml. of 1 percent phosphate buffer at pH 6.0, shake until the powder has dissolved and the capsules have gelatinized and make to 500 ml. with the phosphate buffer. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The average potency of capsules buffered penicillin with pectin hydrolysate is satisfactory if it contains not less than 85 percent of the number of units per capsule it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a) utilizing the contents of 4 capsules.

§ 141.22 *Penicillin bougies*—(a) *Potency.* Proceed as directed in § 141.9 (a).

(b) *Moisture.* Proceed as directed in § 141.7 (c), using 1.0 to 2.0 gm. of bougies dissolved in 10 ml. of dry chloroform if it contains the excipient polyethylene glycol. If it does not contain the excipient polyethylene glycol, proceed as directed in § 141.5 (a).

§ 141.23 *Crystalline penicillin and epinephrine in oil*—(a) *Potency.* Proceed as directed in § 141.7 (a) except the provisions for warming the sample. When examined by the method described in this section the potency of crystalline penicillin and epinephrine in oil is satisfactory if it is 90 percent or more of the potency represented.

(b) *Sterility.* Proceed as directed in § 141.7 (b) except the provision for warming the sample.

(c) *Moisture.* Proceed as directed in § 141.7 (c).

(d) *Epinephrine content*—(1) *Standard curve.* Prepare a stock standard containing 20 mg. of U. S. P. epinephrine reference standard in 100 ml. of phosphate buffer at pH 4.0. This buffer is prepared by adjusting 1 percent phosphate buffer pH 6.0 with 1:100 phosphoric acid (ortho 85 percent) to pH 4.0. The stock standard is stored in the refrigerator and may be used as long as it remains colorless. Transfer 1.0, 2.0, 3.0, 4.0, and 5.0 ml. of the standard to each of five 100-ml. volumetric flasks using transfer pipettes. Add 4.0, 3.0, 2.0, and 1.0 ml. of the phosphate buffer pH 4.0 to the first four flasks respectively to give each a total volume of 5 ml. Add 1.0 ml. of 0.1 N iodine to each flask, shake for one minute, add 2.0 ml. of 0.1 N sodium thiosulfate and mix the solution. Make each flask to a volume of 100 ml. with distilled water. Read the percent light transmission of the colored solutions using a 2.0 cm. cell and a 490 mμ filter in a suitable photoelectric colorimeter. The instrument is balanced so that the 0.2 mg./100 ml. concentration reads 90 percent light transmission. Prepare a standard curve on semilog paper, plotting the percent light transmission on the logarithmic ordinate scale and the concentration on the abscissa.

(2) *Procedure.* Transfer 1.0 ml. of the sample with the aid of a hypodermic syringe and needle to a screw-cap test tube (about 30 ml. capacity), add 5.0 ml. of U. S. P. chloroform and 10.0 ml. of 1 percent phosphate buffer pH 6.0 from a transfer pipette. Shake thoroughly for one minute, centrifuge to separate the layers and carefully withdraw a 5.0 ml. aliquot of the buffer layer using a transfer pipette. Transfer the aliquot to a 50 ml. volumetric flask, add the calculated amount of 1:100 phosphoric acid to bring the pH to 4.0 (amount to be added previously determined by titration of the 1 percent phosphate buffer pH 6.0 with 1:100 phosphoric acid using a pH meter). Add 1.0 ml. of 0.1 N iodine, shake for one minute, add 2.0 ml. of 0.1 N sodium thiosulfate and mix the solution. Make to a volume of 50 ml. with distilled water. Set the colorimeter at 90 percent light transmission for the 0.2 mg./100 ml. standard as directed above and obtain the percent light transmission of the sample. The concentration obtained directly from the standard curve corresponding to the percent light transmission of the sample × 1.05 equals the concentration of the epinephrine per ml. of the sample. Crystalline penicillin and epinephrine in oil is satisfactory if it contains not less than 0.24 or more than 0.36 mg. epinephrine per ml.

§ 141.24 *Aluminum penicillin*—(a) *Potency.* Proceed as directed in § 141.1 (a), using citrate buffer as prepared in § 141.16 (a) in lieu of phosphate buffer.

(b) *Sterility.* Proceed as directed in § 141.2.

(c) *Pyrogens.* Proceed as directed in § 141.3, but in lieu of the directions for preparation of sample in paragraph (b) thereof, prepare sample as follows:

Suspend approximately 60 milligrams in 20 milliliters of pyrogen-free sterile physiological salt solution, adding the salt solution in approximately 1-milliliter aliquots and mixing thoroughly after each addition, utilizing a pyrogen-free glass stirring rod. Centrifuge, warm to 37° C., withdraw the clear supernatant solution, and inject 1 milliliter per kilogram of rabbit.

(d) *Toxicity.* Proceed as directed in § 141.4, utilizing the solution prepared in paragraph (c) of this section.

(e) *Moisture.* Proceed as directed in § 141.5 (a).

(f) *pH.* Proceed as directed in § 141.5 (b), using a saturated solution.

(g) *Penicillin K content.* Proceed as directed in § 141.5 (f).

§ 141.25 *Aluminum penicillin in oil*—(a) *Potency, sterility.* Proceed as directed in § 141.7.

(b) *Moisture.* Proceed as directed in § 141.23 (c).

§ 141.26 *Procaine penicillin*—(a) *Potency.* Proceed as directed in § 141.1, or by the iodometric method as described in § 141.5 (d) (1), except prepare the sample as follows: Dissolve a weighed sample (approximately 50 mg.) in 2.0 ml. of redistilled methanol. Further dilute this solution with sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2.0 mg. per milliliter.

(b) *Sterility.* Proceed as directed in § 141.2.

(c) *Pyrogens.* Proceed as directed in § 141.3, except use physiological salt solution as the diluent.

(d) *Toxicity.* Proceed as directed in § 141.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter.

(e) *Moisture.* Proceed as directed in § 141.7 (c), but in lieu of the directions for preparing the sample in subparagraph (3) thereof prepare the sample and calculate as follows: Accurately weigh about 300 mg. of the sample into a dry titrating vessel, add an excess of the Karl Fischer reagent and back titrate with water-methanol solution until the endpoint is reached.

$$\text{Percent moisture} = \frac{(v_1 - v_2 f) \times e \times 100}{W_s},$$

where W_s = weight of sample in milligrams.

(f) *pH.* Proceed as directed in § 141.5 (b) using a saturated aqueous solution prepared by adding 300 mg. per milliliter.

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141.5 (c).

(h) *Penicillin G content.* Proceed as directed in § 141.5 (c) using the following formula for calculating the percent of procaine penicillin G:

$$\text{Percent of procaine penicillin G} = \frac{\text{N-ethyl piperidine penicillin precipitate} \times 263.1}{\text{Weight of sample in milligrams}}$$

and in lieu of the first four sentences in § 141.5 (c) (2) proceed as follows:

Accurately weigh approximately 100 milligrams of the sample to be tested in a glass test tube or glass vial of approximately 10-milliliter capacity. Add 2 milliliters of water and cool to 0° C. to 5° C. Add 2 milliliters of the amyl acetate solution and 0.5 milliliter of the phosphoric acid solution, stopper and

shake vigorously for aproximately 15 seconds. Add a second 0.5-milliliter portion of the phosphoric acid solution and shake vigorously again. Centrifuge to obtain a clear separation of the two layers (approximately 20 seconds). If any procaine penicillin remains undissolved, add a third portion of 0.5 milliliter of the phosphoric acid solution and repeat the shaking and centrifugation.

(i) *Penicillin K content.* Weigh from 30–35 mg. of the sample to be tested in a glass test tube or glass vial of approximately 10-ml. capacity. Add 2.0 ml. of chloroform U. S. P. and cool the mixture to 0°–5° C. in an ice bath. Add 1.0 ml. of cold 1–4 phosphoric acid solution, stopper and shake vigorously for 15 seconds. Centrifuge to obtain a clear separation of the layers (approximately 20 seconds). After centrifuging, remove 1.0 ml. of the chloroform layer with a pipette or syringe equipped with a suitable needle. Immediately place the 1.0 ml. of chloroform in a 125-ml. separatory funnel containing 29.0 ml. of chloroform and 15.0 ml. of 0.3 M phosphate (Na_2HPO_4 and KH_2PO_4) buffer pH 6.0 at room temperature and shake for 1 minute. Allow the mixture to stand with occasional swirling to settle the droplets of chloroform until the top layer is clear (usually about 10 minutes). Draw off all but about 2 ml. of the lower chloroform layer through a small pledget of cotton into a glass-stoppered flask. Take a 4.0 ml.-aliquot of the buffer solution remaining in the separatory funnel and a 10.0-ml. aliquot of the chloroform solution and determine the milligrams per milliliter of penicillin in each by the iodometric assay procedure described in § 141.5 (e), using 4.0 ml. of the 1N NaOH and 4.0 ml. of the 1.2N HCl for the two above aliquots. Make blank determinations on the same size aliquots. Calculate the percent penicillin in the buffer layer on the basis that the sum of the penicillin found in the buffer layer and in the chloroform layer is 100 percent. The percent penicillin K=(98.46— percent found in buffer) ×3.34.

§ 141.27 *Procaine penicillin in oil*—(a) *Potency.* Proceed as directed in § 141.1, except paragraph (i) thereof and, in lieu of the directions in paragraph (d) of § 141.1, prepare sample as follows: Introduce 1 ml. of the well-shaken sample by means of a 2-ml. hypodermic syringe, into a 50-ml. volumetric flask. Add 3 to 4 cc. of chloroform, shake the flask well, and make to 50 ml. with absolute alcohol. Mix thoroughly, withdraw a 1-ml. aliquot and make the proper estimated dilutions in 1% phosphate buffer at pH 6.0. If the label represents the potency of the procaine penicillin in oil as 100,000 units per milliliter, it is satisfactory if it is 85% or more of the potency so represented; if represented as 300,000 units per milliliter, it is satisfactory if it is 90% or more of the potency so represented.

(b) *Sterility.* Proceed as directed in § 141.7 (b).

(c) *Moisture.* Proceed as directed in § 141.7 (c).

§ 141.28 *Crystalline penicillin for inhalation therapy*—(a) *Potency.* Proceed as directed in § 141.1, or by the iodometric method as described in § 141.5 (d) (1).

(b) *Moisture.* Proceed as directed in § 141.5 (a), except if it is procaine penicillin proceed as directed in § 141.26 (e).

§ 141.29 *Procaine penicillin for aqueous injection*—(a) *Potency.* Proceed as directed in § 141.1, using a 50 percent acetone-water solution to dissolve the sample, or by the iodometric method as described in § 141.5 (d) (1), except dissolve the sample in about 5.0 ml. of redistilled methanol prior to diluting with 1 percent phosphate buffer pH 6.0.

(b) *Sterility.* Proceed as directed in § 141.2, except if it is the aqueous suspension of the drug and it does not contain a preservative, incubate all tubes for 14 days.

(c) *Moisture.* Proceed as directed in § 141.26 (e).

(d) *Pyrogens.* Proceed as directed in § 141.3, except use physiological salt solution as the diluent.

(e) *Toxicity.* Proceed as directed in § 141.4, except use physiological salt solution as the diluent, and inject 0.25 milliliter of a solution containing 4,000 units per milliliter.

(f) *pH.*—(1) *Dry mixture of the drug.* Proceed as directed in § 141.5 (b), using a saturated aqueous solution prepared by adding 300 mg. per milliliter.

(2) *Aqueous suspension of the drug.* Proceed as directed in § 141.5 (b), using the undiluted aqueous suspension.

§ 141.30 *Ephedrine penicillin*—(a) *Potency.* Proceed as directed in § 141.1, or by the iodometric method as described in § 141.5 (d) (1), except dilute the sample with sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2.0 mg. per milliliter.

(b) *Sterility.* Proceed as directed in § 141.2.

(c) *Pyrogens.* Proceed as directed in § 141.3.

(d) *Toxicity.* Proceed as directed in § 141.4.

(e) *Moisture.* Proceed as directed in § 141.5 (a).

(f) *pH.* Proceed as directed in § 141.5 (b).

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141.5 (c).

(h) *Penicillin G content.* Proceed as directed in § 141.5 (e) using an accurately weighed sample of approximately 80 mg. and the following formula for calculating the percent of ephedrine penicillin G:

$$\text{Percent of ephedrine penicillin G} = \frac{\text{Milligrams N-ethyl piperidine penicillin precipitate} \times 223.2}{\text{Weight of sample in milligrams}}$$

(i) *Penicillin K content.* Proceed as directed in § 141.5 (f).

§ 141.31 *Ephedrine penicillin tablets*—(a) *Potency.* Proceed as directed in § 141.9 (a) or by the iodometric method as described in § 141.5 (d) (1), using 6 tablets dissolved in sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2,000 units per milliliter.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.32 *Procaine penicillin and buffered crystalline penicillin for aqueous injection*—(a) *Potency, sterility, moisture, pyrogens, toxicity, pH.* Proceed as directed in § 141.29.

(b) *Buffered crystalline penicillin content*—(1) *Preparation of sample.* Add the indicated amount of distilled water to the contents of a vial of the sample and shake well. Withdraw 1.0 ml. of the suspension with a hypodermic syringe and place in a 15-ml. centrifuge tube. Add 9.1 ml. of 20% sodium sulfate solution, shake well, and centrifuge to obtain a clear solution.

(2) *Iodometric assay for total penicillin.* Dilute a 5.0-ml. aliquot of the clear solution prepared in accordance with subparagraph (1) of this paragraph to 50 ml. with 1 percent phosphate buffer at pH 6.0. Determine the total quantity of penicillin in a 2.0-ml. aliquot of this solution by the iodometric assay procedure described in § 141.5 (d).

(3) *Colorimetric determination of procaine penicillin.* (i) Transfer a 2.0-ml. aliquot of the solution prepared in subparagraph (2) of this paragraph to a 50-ml. volumetric flask and add 8.0 ml. of distilled water. Determine the quantity of procaine penicillin in this solution by the following method:

(ii) *Reagents*—(a) *Sodium nitrite solution.* Dissolve 0.1 gm. of sodium nitrite in 100 ml. distilled water. Prepare fresh solution every other day.

(b) *Ammonium sulfamate solution.* Dissolve 0.5 gm. of ammonium sulfamate in 100 ml. distilled water.

(c) *N-1(1-naphthyl)-ethylenediamine solution.* Dissolve 0.1 gm. of N-(1-naphthyl)-ethylenediamine dihydrochloride in 100 ml. distilled water. Prepare fresh solution every other day.

(iii) *Standard curve.* Prepare a standard solution containing 27.55 mg. of procaine hydrochloride U. S. P. in a liter of distilled water (each milliliter of the standard solution is equivalent to 60 units of procaine penicillin). Transfer, respectively, 1.0, 2.0, 3.0, 4.0, and 5.0 ml. of the standard solution and 5.0 ml. of distilled water to each of six 25-ml. volumetric flasks. Add 4.0, 3.0, 2.0, and 1.0 ml. of water to the first four flasks, respectively, to give each a volume of 5.0 ml. To each flask add 0.5 ml. of 4N HCl, 1.0 ml. of the sodium nitrite solution, 1.0 ml. of the ammonium sulfamate, and 1.0 ml. of the N-(1-naphthyl)-ethylenediamine solution, with mixing after each addition. Make each flask to volume of 50 ml. with distilled water. Read the percent light transmission of the colored solutions using a 2.0-cm. cell and a 550 $/m\mu$ filter in a suitable photoelectric colorimeter. The instrument is balanced so that the zero concentration reads 100% light transmission. Prepare a standard curve on semilog paper, plotting the percent light transmission on the logarithmic ordinate scale and the concentration of units of procaine penicillin on the abscissa.

(iv) *Procedure.* By means of a volumetric pipette transfer to a 50-ml. volumetric flask 2.0 ml. of the solution prepared in subparagraph (2) of this paragraph. Add 0.5 ml. of 4N HCl, 1.0 ml. of the sodium nitrite solution, 1.0 ml. of the ammonium sulfamate solution, and 1.0 ml. of the N-(1-naphthyl)-ethylenediamine solution with mixing after each addition. Make to 50 ml. with distilled water. Set the colorimeter at 100% light transmission with the 0% concentration blank as directed above and obtain the percent light transmission of the sample. The concentration obtained directly from the standard curve corresponding to the percent light transmission of the sample equals the concentration of procaine penicillin in 2 ml. of the solution prepared in subparagraph (2) of this paragraph. The content of buffered crystalline penicillin in 1.0 ml. of the suspension is equal to the difference between the total number of units of penicillin in 2.0 ml. of the solution as determined by subparagraph (2) of this paragraph and the total number of units of procaine penicillin in 2.0 ml. of this same solution as determined above, multiplied by 50. The content of buffered crystalline penicillin in the batch is satisfactory when determined by the method described in this paragraph if it is not less than 85% of that which it is represented to contain.

(c) *Procaine penicillin.* The procaine penicillin content of the batch is the difference between the potency determined by the method described in paragraph (a) of this section and the content of buffered crystalline penicillin determined by the method described in paragraph (b) of this section. The procaine penicillin content of the batch is satisfactory when determined by the method described in this paragraph if it is not less than 85% of that which it is represented to contain.

§ 141.33 *Buffered penicillin powder.* Proceed as directed in §§ 141.1 and 141.5 (a).

§ 141.34 *Procaine penicillin and crystalline penicillin in oil*—(a) *Total potency.* Proceed as directed in § 141.27 (a) or by the iodometric assay procedure described in § 141.5 (e), using in the latter procedure a 0.5-ml. aliquot of the solution prepared as follows: Introduce 1 ml. of the well-shaken sample, by means of a hypodermic syringe, into a 50-ml. volumetric flask. Make to 50 ml. with chloroform-absolute alcohol (1+1) solvent and shake well.

(b) *Crystalline penicillin.* Proceed as directed in § 141.32 (b), except prepare the sample as follows: Introduce 1 ml. of the well-shaken sample, by means of a hypodermic syringe, into a 30-ml. centrifuge tube equipped with a screw cap. Add 10.0 ml. of chloroform and 10.0 ml. of a 20% sodium sulfate solution, shake well for about 1 minute and centrifuge to obtain a clear upper layer.

(c) *Procaine penicillin.* The difference between the total penicillin as determined by paragraph (a) of this section and the crystalline penicillin as determined by paragraph (b) of this section represents the amount of procaine penicillin present.

(d) The procaine penicillin and the crystalline penicillin content of the batch are satisfactory when assayed by the methods described in this section if each is not less than 85% of that which it is represented to contain.

(e) *Sterility.* Proceed as directed in § 141.7 (b).

(f) *Moisture.* Proceed as directed in § 141.7 (c).

§ 141.35 *Penicillin-streptomycin ointment, penicillin-dihydrostreptomycin ointment*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141.8 (a), except the last sentence of that paragraph. Its content of penicillin is satisfactory if it contains not less than 85% of the number of units per gram of ointment that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141.101, except paragraphs (j) and (k) thereof, and in lieu of the directions in paragraph (d) of § 141.101, prepare the sample as follows: Accurately weigh the container and contents and place 0.5 to 1.0 gm. into a separatory funnel containing approximately 50 ml. of peroxide-free ether. Reweigh the container to obtain the weight of the ointment used in the test. Shake ointment and ether until homogeneous. Shake with a 20-ml. portion of buffer at pH 8.0. Remove the buffer layer and repeat the extraction with three 20-ml. quantities of buffer. Combine the extracts, add sufficient penicillinase to completely inactivate the penicillin, make up to 100 ml. and let inactivate for 1 hour. After inactivation, make the proper estimated dilutions in buffer at pH 8.0. Its content of streptomycin is satisfactory if it contains not less than 85% of the number of milligrams per gram of ointment that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85% of the number of milligrams per gram of ointment that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.8 (b).

§ 141.36 *Penicillin-streptomycin bougies, penicillin-dihydrostreptomycin bougies*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141.9 (a), except the last sentence of that paragraph. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Using twelve bougies, proceed as directed in § 141.101, except paragraph (k) of that section, and in addition to the directions for the preparation of the sample in paragraph (e) of § 141.101, add sufficient penicillinase to the solution under test to completely inactivate the penicillin present. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Using the dihydrostreptomycin working standard as a standard of comparison and using twelve bougies, proceed as directed in § 141.101 (j), except that in addition to the directions for the preparation of the sample in subparagraph (3) of that paragraph add sufficient penicillinase to the solution under test to completely inactivate the penicillin present. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.22 (b).

§ 141.37 *Penicillin-bacitracin ointment*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141.8 (a), except the last sentence of that paragraph. Its content of penicillin is satisfactory if it contains not less than 85% of the number of units it is represented to contain.

(2) *Bacitracin content.* Proceed as directed in § 141.402 (a), except that sufficient penicillinase is added to the sample under test to completely inactivate the penicillin present. Its content of bacitracin is satisfactory if it contains not less than 85% of the number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.8 (b).

§ 141.38 *Procaine penicillin and streptomycin in oil, procaine penicillin and dihydrostreptomycin in oil*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141.27 (a) except the last sentence thereof. Its content of penicillin is satisfactory if it contains not less than 85% of the number of units per milliliter that it is represented to contain.

(2) *Streptomycin content.* Using 1 ml. as the test sample proceed as directed in § 141.35 (a) (2). Its content of streptomycin is satisfactory if it contains not less than 85% of the number of milligrams per milliliter that it is represented to contain.

(3) *Dihydrostreptomycin content.* Using 1 ml. as the test sample proceed as directed in § 141.35 (a) (3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85% of the number of milligrams per milliliter that it is represented to contain.

(b) *Moisture.* Using 1 ml. as the test sample proceed as directed in § 141.7 (c).

§ 141.39 *Penicillin and streptomycin, penicillin and dihydrostreptomycin*—(a) *Potency*—(1) *Total penicillin content.* Proceed as directed in § 141.1.

(2) *Procaine penicillin and sodium or potassium penicillin*—(i) *Procaine penicillin content.* Proceed as directed in § 141.32 (b) (3), except prepare the sample as follows: Add the indicated amount of distilled water to the contents of a vial of the sample and shake well. Withdraw one dose of the suspension or solution with a hypodermic syringe, place in a 250-ml. volumetric flask and make to 250 ml. with 1% phosphate buffer pH 6.0. Dilute a 5.0 ml. aliquot of this solution to 100 ml. with distilled water. The procaine penicillin found in a 2-ml. aliquot of this solution×2500 gives the procaine penicillin content of one dose of the preparation under test. The content of procaine penicillin in the batch is satisfactory when determined by the method

described in this subdivision if it is not less than 85% of that which it is represented to contain.

(ii) *Sodium or potassium penicillin content.* Determine the total penicillin content as directed under subparagraph (1) of this paragraph. Obtain the sodium or potassium penicillin content by subtracting the procaine penicillin content obtained under subdivision (i) of this subparagraph from the total penicillin content. The sodium or potassium penicillin content of the batch is satisfactory if it is not less than 85% of that which it is represented to contain.

(3) *Streptomycin content.* Proceed as directed in § 141.101 (j) and (k).

(4) *Dihydrostreptomycin content.* Proceed as directed in § 141.108 (a).

(b) *Sterility.* If the sample contains streptomycin, proceed as directed in § 141.102, except that M. pyogenes var. aureus (PCI 1214) is used as the control-test organism. If the sample contains dihydrostreptomycin add sufficient sterile penicillinase to completely inactivate the penicillin and proceed as directed in § 141.108 (c).

(c) *Toxicity.* Proceed as directed in § 141.103.

(d) *Pyrogens.* Proceed as directed in § 141.104.

(e) *Moisture.* Proceed as directed in § 141.26 (a).

(f) *pH.* Proceed as directed in § 141.5 (b), using the solution or suspension resulting when the amount of diluent recommended in the labeling is added.

§ 141.40 *Penicillin tooth powder—*(a) *Potency.* Proceed as directed in § 141.1.

(b) *Moisture.* Proceed as directed in § 141.7 (c), but in lieu of the directions for preparing the sample in subparagraph (3) thereof prepare the sample and calculate as follows: Accurately weigh about 1 gm. of the sample into a dry titrating vessel. Add an excess of the Karl Fischer reagent and back titrate immediately with water-methanol solution until the end point is reached. (The entire operation from the addition of the Karl Fischer reagent until the end point is reached should not exceed 1 minute.)

$$\text{Percent moisture} = \frac{(V_1 - V_2 f) \times 100}{W_s},$$

where W_s = weight of sample in milligrams.

§ 141.101 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency—*(a) *Cylinders (cups).* Use cylinders described under § 141.1 (a).

(b) *Culture media.* Using ingredients that conform to the standards prescribed by the U. S. P. or N. F., make nutrient agar for the seed and base layers:

Peptone	5.0 gm.
Beef extract	3.0 gm.
Agar	15.0 gm.
Distilled water q. s.	1,000.0 ml.

pH 7.8 to 8.0 after sterilization.

(c) *Working standard.* Keep the working standard (obtained from the Food and Drug Administration) at room temperature in tightly stoppered vials, which in turn are kept in larger stoppered vials containing anhydrous magnesium perchlorate. Dry an appropriate amount of the working standard as described in § 141.5 (a) (the moisture-free working standard has a potency of 780 micrograms per milligram). Dissolve the weight of dry working standard obtained in 0.05 M potassium phosphate buffer (pH 6.0). Keep this stock solution at a temperature of about 15° C.; do not use it later than 30 days after it is made.

(d) *Standard curve.* Prepare daily in 0.10 M potassium phosphate buffer (pH 7.8 to 8.0) a 20 mcg./ml. solution from the stock solution described in § 141.101 (c). Transfer to ten 100-ml. volumetric flasks, containing the same buffer, the required quantities of this 20 mcg./ml. solution to give 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, and 1.5 mcg./ml. solutions. A total of 27 plates is used in the preparation of the standard curve, three plates for each solution except the 1.0 mcg./ml. solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill 3 cylinders with the 1.0 mcg./ml. standard and the other 3 cylinders with the concentration under test. Thus there will be 81 one microgram determinations and 9 determinations for each of the other points on the curve. After the plates have incubated read the diameters of the circles of inhibition. Average the readings of the 1.0 mcg./ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings of the 1.0 mcg./ml. concentration. The average of the 81 readings of the 1.0 mcg./ml. concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 mcg./ml. reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8 unit concentration, the average of the 81 readings of the 1.0 mcg./ml. concentration is 16.5 mm. and the average of the 1.0 mcg./ml. concentration of this set of 3 plates is 16.3 mm. the correction is 0.2 mm. If the average readings of the 0.8 mcg./ml. concentration of these same 3 plates is 15.9 mm. the corrected value is then 16.1 mm. Plot these corrected values including the average of the 1.0 mcg./ml. concentration on 2 cycle semi-log paper using the concentration in mcg./ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. The ten points selected to determine the curve are arbitrary and should be so chosen that the limits of the curve will fill the needs of the laboratory. However, the potency of the sample under test should fall in the interval of from 60 percent to 150 percent of the correction point of the standard curve.

(e) *Preparation of sample.* Dissolve volumetrically in sterile, distilled water, the sample to be tested to make a convenient stock solution. Further dilute this solution volumetrically to contain 100 mcg. of streptomycin base (estimated) per ml. Transfer 1.0 ml. of this 100 mcg. (estimated) per ml. solution to a 100 ml. flask and make up to volume with 0.10 M potassium phosphate buffer (pH 7.8 to 8.0). Use this last dilution in the assay for potency.

(f) *Preparation of spore suspension.* The test organism is Bacillus subtilis (American Type Culture Collection 6633). Maintain the test organism on nutrient agar prepared as described in § 141.1 (b) (1). Prepare a spore suspension by growing the organism in Roux bottles on agar of this same composition for one week at 32° C.–35° C. Suspend the spores in sterile distilled water and heat for 30 minutes at 65° C. Wash the spore suspension three times with sterile distilled water, heat again for 30 minutes at 65° C. and resuspend in sterile distilled water. Maintain the spore suspension at approximately 15° C. Determine by appropriate tests the quantity of spore suspension to be added to each 100 ml. of agar for the secondary layer that will give sharp clear zones of inhibition.

(g) *Preparation of plates.* Add 21 ml. of agar described in paragraph (b) of this section to each Petri dish (20×100 mm.). Melt the agar to be used for the secondary layer, cool to 55 to 60° C. and add the spore suspension prepared in § 141.101 (f). Mix thoroughly and add 4 ml. to each of the plates containing the 21 ml. of the uninoculated agar. Tilt the plates back and forth to spread the inoculated agar evenly over the surface. Refrigerate until ready to add streptomycin (at least 1 hour).

(h) *Plate assay.* Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on 2.8 cm. radius. Use three plates for each sample. Fill three cylinders on each plate with the 1.0 mcg./ml. standard and three cylinders with the 1.0 mcg./ml. (estimated) sample, alternating standard and sample. Incubate the plates for 16 to 18 hours at 32° C.–35° C. and measure the diameter of each circle of inhibition.

(i) *Estimation of potency.* Average the zone readings of the standard and average the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 1.0 mcg. zone size of the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 mcg. value on the curve. From the curve read the potencies corresponding to these corrected values of zone sizes.

(j) *Turbidimetric assay.* In lieu of the plate assay method described in paragraph (h) of this section the sample may be assayed for potency by the following turbidimetric method: (1) Employ the agar described in paragraph (b) of this section (adjusted to a final pH 7.0) for maintaining the test organism, which is Klebsiella pneumoniae (P. C. I. 602) non-capsulated. Transfer stock cultures every two weeks for test purposes. Transfer the organism to fresh agar slants and incubate at 32° C.–35° C. for 6 hours. Suspend the growth from two or three of these slants in sterile distilled water and add ap-

proximately 5 ml. of culture suspension to each of two Roux bottles containing the agar described in paragraph (b) of this section. Incubate the bottles for six hours at 32° C.–35° C., harvest the growth and suspend in sufficient sterile distilled water to give a light transmission reading of 80 percent using a filter at 6500 Angstrom units in a photoelectric colorimeter. Keep the resulting suspension of organisms in the refrigerator and use for a period not to exceed two weeks. Prepare a daily inoculum by adding 6.0 ml. of this suspension to each 100 ml. of the nutrient broth prepared as directed in § 141.1 (b) (3) cooled to a temperature of approximately 15° C.

(2) *Working standard solutions.* Add the following amounts of a 1000 microgram per ml. solution prepared from the stock solution described in paragraph (c) of this section to 100 ml. volumetric flasks containing sterile distilled water and bring to volume to give the working stock solutions tabulated below. These 9 flasks are well stoppered and maintained at approximately 15° C. for one month. Prepare final dilutions daily by adding 2.1 ml. of each of these 9 working stock solutions to 4.8 ml. of sterile distilled water. Add 1.0 ml. of each final dilution to each of six 14 x 124 mm. tubes (total 54 tubes). Add 9.0 ml. of inoculated broth described in subparagraph (1) of this paragraph to each tube and place immediately in a 32° C.–35° C. water bath for 4 hours. The final concentration of streptomycin per ml. of broth is also included in the table below.

Amount of standard solution (1,000 mcg./ml.)	Working conc./ml. (also percent conc.)	Final conc. (mcg./ml.) after addition of distilled water and broth
Ml.	*Mcg.*	*Mcg.*
6.0	60	1.8
7.0	70	2.1
8.0	80	2.4
9.0	90	2.7
10.0	100	3.0
11.0	110	3.3
12.0	120	3.6
13.0	130	3.9
14.0	140	4.2

(3) *Preparation of sample.* Dilute the sample under test with sterile distilled water to contain 100 mcg./ml. (estimated). To 2.1 ml. of the sample add 4.8 ml. sterile distilled water. Add 1.0 ml. of this dilution to each of six 14 x 124 mm. tubes. Add 9.0 ml. of the inoculated broth described in subparagraph (1) of this paragraph to each tube and place immediately in a 32° C.–35° C. water bath for 4 hours. A control tube containing 1.0 ml. of distilled water and 9.0 ml. of the inoculated broth is similarly incubated. After incubation, add 4 drops of formalin to each tube, and read the light transmission in a photoelectric colorimeter, using a broad band filter having a wave length of 5,300 Angstrom units.

(4) *Estimation of potency.* Average the light transmission readings for each concentration of the standard. Plot these values on cross section paper, employing average light transmission readings as the ordinate, and streptomycin concentration per ml. of broth as the abscissa. Prepare the standard curve by connecting successive points with a straightedge. Since the final concentration of streptomycin per ml. of broth is equivalent to the concentration per ml. of the working stock solution (see table in subparagraph (2) of this paragraph) the latter concentrations for each concentration level of the standard may be expressed as percent and substituted on the abscissa of the standard curve. If this is done the percent potency of the sample under test may be read directly from the standard curve.

(k) *Potency.* The potency of streptomycin is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 90 percent of the number of grams they are represented to contain.

§ 141.102 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; sterility*—(a) *Culture medium.* Prepare fluid thioglycollate medium as described in § 141.2 (a).

(b) *Conduct of test.* Add aseptically 20 ml. of sterile distilled water to the sample under test. (This will give a concentration of approximately 50 mg. of streptomycin per ml. with the 1 gm. vial.) Transfer the equivalent of 25 mg. of this solution to 5 ml. of a sterile solution of 1:300 hydroxylamine hydrochloride adjusted to pH 6.0 with sodium hydroxide. The hydroxylamine hydrochloride is sterilized at 15 lbs. pressure (121° C.) for 20 minutes and prepared once a week. Mix thoroughly and let stand for one hour. Transfer 1.0 ml. of the inactivated streptomycin to each of four tubes containing 15 ml. of fluid thioglycollate medium. Inoculate one of these tubes with 1.0 ml. of a 1:1000 dilution of a 3 to 4 hour broth (§ 141.101 (j) (1)) culture of Klebsiella pneumoniae (P. C. I. 602) and incubate all four tubes for four days at 32° C.–35° C. The inoculated tube should show growth at the end of four days; if so and no other tube shows growth, the sample is sterile.

§ 141.103 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; toxicity.* Proceed as directed in § 141.4 using as a test dose 0.5 ml. of a solution containing 2 mg./ml.

§ 141.104 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; pyrogens.* Proceed as directed in § 141.3 using as a test dose 1.0 ml. per kg. of a solution containing 10 mg./ml.

§ 141.105 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; histamine.* Use a healthy adult cat as the test animal. Determine weight and place under general anesthesia by employing sufficient (150 mg./kg.) sodium phenobarbital administered intraperitoneally. Surgically expose the right carotid separating it completely from all surrounding structures, including the vagus nerve, by blunt dissection and cannulate. Surgically expose the femoral vein. Start the recording kymograph and inspect the tracings for amplitude of excursion and relative stability of pressure. Determine the sensitivity of the animal by injecting into the femoral vein standard solutions of histamine made to contain the equivalent of 1.0 mcg. of histamine base per ml. Make injections at not less than 5-minute intervals using doses of 0.05, 0.1, and 0.15 mcg. of histamine base per kg. Repeat these injections, disregarding the first series of readings, until the drop given by equivalent doses of histamine is relatively uniform. The fall in blood pressure given by 0.1 mcg./kg. of histamine base (not less than 20 mm. of mercury) is subsequently employed as the standard in testing samples. The histamine standard is supplied on request. Inject 3 mg./kg. of the sample of streptomycin per ml. maintaining the five-minute injection schedule. If a significant drop is encountered the dose is repeated after the animal has been retested with the standard histamine. The animal may be used as long as it remains reasonably stable and responsive to histamine. The product is satisfactory if the fall in blood pressure obtained with 3 mg. of streptomycin per kilogram of body weight is no greater than the fall obtained with 0.1 microgram of histamine base per kilogram of body weight. (Dogs may be substituted for cats in this test provided the ratio of the doses of streptomycin and histamine employed is the same.)

§ 141.106 *Streptomycin sulphate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride*—(a) *Moisture.* Proceed as directed in § 141.5 (a).

(b) *pH.* Proceed as directed in § 141.5 (b) using a solution with a concentration of 0.2 gm./ml.

§ 141.107 *Streptomycin ointment, dihydrostreptomycin ointment*—(a) *Streptomycin content.* (1) Proceed as directed in § 141.101, except paragraphs (j) and (k) thereof, and in lieu of the directions in paragraph (e) of § 141.101, prepare the sample as follows:

Accurately weigh the tube and contents and squeeze approximately 1.0 gm. into a blending jar containing 50 ml. of 0.10 M potassium phosphate buffer (pH 7.8 to 8.0). Reweigh the tube to obtain weight of ointment used in the test. Using a high-speed blender, blend the mixture for 3 minutes. Dilute an aliquot of the mixture to contain 100 mcg. of streptomycin base (estimated) per milliliter. Transfer 1.0 ml. of this solution to a 100-ml. flask and make up to volume with 0.10 M potassium phosphate buffer (pH 7.8 to 8.0). Use this last dilution in the assay for potency. The potency of streptomycin ointment is satisfactory if it contains not less than 85 percent of the number of micrograms of streptomycin base per gram it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85% of the number of micrograms of dihydrostreptomycin

base per gram it is represented to contain.

§ 141.108 *Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride*—(a) *Potency.* Using the dihydrostreptomycin working standard as a standard of comparison, proceed as directed in § 141.101 (j) and (k).

(b) *Content of streptomycin sulfate or streptomycin hydrochloride*—(1) *Reagents.* (i) 10 percent ferric chloride stock solution. Dissolve 5 gm. of $FeCl_3 6H_2O$ in 50 ml. 0.1N HCl.

(ii) 0.25 percent ferric chloride solution—Dilute 2.5 ml. of 10 percent ferric chloride in 0.1N HCl to 100 ml. with 0.01N HCl. Prepare the solution fresh daily.

(2) *Standard curve.* Prepare a stock aqueous solution of the Food and Drug Administration working standard containing 1.0 mg. of streptomycin base per milliliter. Store this standard solution in the refrigerator and use for no longer than 2 weeks. Transfer 1.0, 2.0, 3.0, 4.0, and 5.0 ml. of this standard solution and 10 ml. of distilled water to each of six 25-ml. volumetric flasks. Add 9.0, 8.0, 7.0, and 6.0 ml. of distilled water to the first four tubes, respectively, to give each a total volume of 10 ml. To each add 2.0 ml. of 1N NaOH and then heat the flasks in a boiling water bath for 10 minutes. Cool the flasks in ice water for 3 minutes and acidify the solutions with 2.0 ml. of 1.2N HCl. To each flask add 5.0 ml. of 0.25% ferric chloride reagent, make to volume with distilled water, and mix thoroughly. Transfer the colored solutions to 2.0-cm. absorption cells and measure the percent light transmission at 550 mμ in a suitable photoelectric colorimeter. Set the colorimeter at 100% light transmission for the zero concentration and then obtain the percent light transmission of the sample. Prepare a standard curve on semilog paper, plotting the percent light transmission on the logarithmic ordinate scale and the concentration of streptomycin base on the abscissa.

(3) *Procedure.* Dilute the contents of a 1-gm. vial to 50 ml. with distilled water (dilute vials containing larger quantities to make solutions having the same concentration). Transfer a 10-ml. aliquot of this solution to a 25-ml. volumetric flask, add 2.0 ml. of 1N NaOH and heat in a boiling water bath for 10 minutes. Cool in ice water for 3 minutes and acidify the solution with 2.0 ml. of 1.2N HCl. Add 5.0 ml. of 0.25% ferric chloride reagent. Make to volume with distilled water. Transfer the colored solution to a 2.0-cm. absorption cell and measure the percent light transmission at 550 mμ in a suitable photoelectric colorimeter. Set the colorimeter at 100% light transmission for the zero concentration and then obtain the percent light transmission of the sample. The concentration of streptomycin obtained directly from the standard curve corresponding to the percent light transmission of the sample, times 500, divided by the total milligrams per vial obtained by biological assay, equals the percent of streptomycin.

(c) *Sterility*—(1) *Culture medium.* Prepare fluid thioglycollate medium as described in § 141.2 (a).

(2) *Conduct of test.* Add aseptically to each of two tubes containing approximately 15 ml. of fluid thioglycollate medium 1.0 ml. of a 5000-mcg. per milliliter dilution in sterile distilled water of the dihydrostreptomycin under test. Add 0.1 ml. of the 5000-mcg. per milliliter dilution to two additional tubes of thioglycollate medium. Incubate at 32° C.–35° C. for 4 days. If no tube shows growth the sample is satisfactory. This method will demonstrate only those organisms which are not susceptible to this concentration of dihydrostreptomycin.

(d) *Toxicity, pyrogens, histamine, moisture, pH, crystallinity.* Proceed as directed in §§ 141.103, 141.104, 141.105, 141.106, and 141.5 (c).

§ 141.109 *Streptomycin tablets, dihydrostreptomycin tablets*—(a) *Potency*—(1) *Streptomycin content.* Using 12 tablets, proceed as directed in § 141.101, except paragraph (k) of that section. The average potency of streptomycin tablets is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. The average potency of dihydrostreptomycin tablets is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.110 *Streptomycin for topical use*—(a) *Potency.* Proceed as directed in § 141.101, except paragraph (k) thereof. The potency of streptomycin for topical use is satisfactory if the immediate containers are represented to contain:

(1) Less than 500 mg. and contain 85% or more of the number of milligrams so represented;

(2) More than 500 mg. and contain 90% or more of the number of milligrams so represented.

(b) *Sterility, toxicity, pyrogens, histamine, moisture, pH.* Proceed as directed in §§ 141.102, 141.103, 141.104, 141.105, and 141.106.

§ 141.111 *Streptomycin sulfate solution, dihydrostreptomycin sulfate solution, crystalline dihydrostreptomycin sulfate solution.* Proceed as directed in §§ 141.101, 141.102, 141.103, 141.104, 141.105, and 141.106 (b), if it is streptomycin sulfate solution. If it is dihydrostreptomycin sulfate solution or crystalline dihydrostreptomycin sulfate solution, proceed as directed in § 141.108.

§ 141.112 *Streptomycin-polymyxin-bacitracin tablets*—(a) *Tablets*—(1) *Potency*—(i) *Streptomycin content.* Using 12 tablets, proceed as directed in § 141.101, except paragraphs (j) and (k) of that section. Its content of streptomycin is satisfactory if it contains not less than 85% of the number of milligrams that it is represented to contain.

(ii) *Polymyxin content.* Using an aliquot of the solution prepared under subdivision (i) of this subparagraph, proceed as directed in paragraph (b) of this section. Its content of polymyxin is satisfactory if it contains not less than 85% of the number of units that it is represented to contain.

(iii) *Bacitracin content.* Using an aliquot of the solution prepared under subdivision (i) of this subparagraph, proceed as directed in § 141.403 (a), except the last sentence of that paragraph and except that sufficient semi-carbazide 0.5% solution (pH 6.5–7.0) is added to inactivate (1 hour at room temperature) the streptomycin contained in the solution. Its content of bacitracin is satisfactory if it contains not less than 85% of the number of units that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141.5 (a).

(b) *Polymyxin used in making the tablets*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described under § 141.1 (a).

(ii) *Culture medium.* Using ingredients that conform to the standards prescribed, if any, by the U. S. P. or N. F., make nutrient agar for the seed and base layers:

Pancreatic digest of casein	15.0 gm.
Papaic digest of soybean	5.0 gm.
Sodium chloride	5.0 gm.
Agar	15.0 gm.
Distilled water, q. s.	1,000.0 ml.

In lieu of preparing the medium from the individual ingredients as specified, it may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium. Minor modifications of the specified individual ingredients are permissible if the resulting medium possesses growth-promoting properties at least equal to the medium described.

(iii) *Working standard.* Weigh out a sufficient quantity of the working standard (obtained from the Food and Drug Administration) and make a convenient stock solution by diluting with glycine buffer, which is prepared as follows:

Glycine	3.6 gm.
Sodium chloride	3.0 gm.
Distilled water, q. s.	1,000.0 ml.

(Adjust to pH 2.0 with concentrated HCl.)

(iv) *Standard curve.* Prepare daily a standard curve as directed in § 141.101 (d), using solutions of the polymyxin working standard in glycine buffer (described under subdivision (iii) of this subparagraph) in concentrations of 200, 400, 600, 800, 1,000, 1,200, 1,400, 1,600, 1,800, and 2,000 units per milliliter. The 1,000 units-per-milliliter concentration is used as the reference point.

(v) *Preparation of test organism.* The test organism is Brucella bronchiseptica (American Type Culture Collection 4617) which is maintained on agar described under subdivision (ii) of this subparagraph. Prepare the inoculum by transferring the culture from the agar slant into sterile broth, and incubate overnight at 32° C.–35° C. Prepare the broth used as follows:

Pancreatic digest of casein	17.0 gm.
Papaic digest of soybean	3.0 gm.
Sodium chloride	5.0 gm.
Dipotassium phosphate	2.5 gm.
Dextrose	2.5 gm.
Distilled water, q. s.	1,000.0 ml.

For the seed layer use approximately a 0.5% inoculum.

(vi) *Preparation of plates.* Using the agar described in subdivision (ii) of this subparagraph, prepare the plates as described in § 141.101 (g).

(vii) *Assay.* Dissolve volumetrically into the sterile glycine buffer described in subdivision (iii) of this subparagraph the sample to be tested to a final concentration of 1,000 units (estimated) per milliliter and proceed as directed in § 141.101 (h) and (i).

(2) *Toxicity.* Proceed as directed in § 141.4, using 0.5 ml. of a solution prepared by diluting the sample to approximately 1,200 units per milliliter with physiological salt solution.

§ 141.113 *Streptomycin syrup*—(a) *Potency.* Proceed as directed in § 141.101, except paragraph (k) thereof. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin per milliliter it is represented to contain.

§ 141.201 *Aureomycin hydrochloride*—(a) *Potency*—(1) *Cylinders (cups).* Use cylinders described under § 141.1 (a).

(2) *Culture media.* Use a medium described under § 141.1 (b) (1) and (2) for the seed layer and the base layer. Use a nutrient broth described under § 141.1 (b) (3) for preparing a suspension of the test organism.

(3) *Working standard.* Weigh out carefully an appropriate amount of the aureomycin working standard and dilute to 1,000 micrograms per milliliter in water. The standard solution, when refrigerated, may be used for 7 days. The standard solution may be preserved for at least 2 months by freezing in small aliquots. Each aliquot should be sufficient for one day's use only.

(4) *Preparation of sample.* Dissolve the sample to be tested in sterile distilled water to make an appropriate stock solution. Make the final dilution in 1 percent phosphate buffer pH 6.0 to contain 20 micrograms per milliliter.

(5) *Preparation of suspension.* The test organism is Sarcina lutea (P. C. I. 1001 and American Type Culture Collection 9341). Maintain the test organism on slants of nutrient agar prepared as in subparagraph (2) of this paragraph, and transfer to a fresh agar slant once a week. Prepare a suspension of the test organism as follows: Streak an agar slant heavily with a test organism. Wash the growth off with 3 milliliters of nutrient broth. Use the suspension so obtained to inoculate the surface of a Roux bottle containing 300 milliliters of the nutrient agar. Spread the suspension over the entire surface with the aid of sterile glass beads. Incubate for 24 hours at 26° C. Wash growth from the agar surface with 25 milliliters of nutrient broth prepared as in subparagraph (2) of this paragraph. If an aliquot of this bulk suspension, when diluted with nutrient broth 1:10, gives 10 percent light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6500 Angstrom units, the bulk suspension is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:10 gives 10 percent of light transmission. (The adjusted bulk suspension only and not the 1:10 dilution of it is used in preparing the seed layer.) The bulk suspension may be used for at least one week. Add 0.5 to 1.0 milliliter of the adjusted bulk suspension to 100 milliliters of agar which has been melted and cooled to 48° C.

(6) *Preparation of plates.* Add 21 milliliters of the agar prepared as in subparagraph (2) of this paragraph to each Petri dish (20 x 100 mm.) Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. Add 4.0 milliliters of the inoculum as prepared in subparagraph (5) of this paragraph to each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(7) *Assay.* Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 20 micrograms per milliliter standard and three cylinders with the 20 micrograms per milliliter (estimated) sample, alternating standard and sample. At the same time prepare a standard curve using concentrations of the standard of 8.0, 10.0, 12.0, 16.0, 20.0, 24.0, 28.0, 32.0, and 36.0 micrograms per milliliter in 1 percent phosphate buffer pH 6.0. A total of 24 plates is used in the preparation of this standard curve, three plates for each solution, except the 20 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill three cylinders with the 20 micrograms per milliliter standard and the other three cylinders with the concentration of the standard under test. Thus, there will be 72 twenty-microgram determinations and nine determinations for each of the other points on the curve. Incubate the plates for 16 to 18 hours at 32° C.–35° C. and measure the diameter of each circle of inhibition. Average the readings of the 20 micrograms per milliliter concentration and the readings of the point tested for each set of three plates and average also all 72 readings of the 20 micrograms per milliliter concentration. The average of the 72 readings and the 20 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 20 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 16 micrograms per milliliter concentration the average of the 72 readings of the 20 micrograms per milliliter concentration is 18.0 millimeters, and the average of the 20 micrograms per milliliter concentration of this set of three plates is 17.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 16 micrograms per milliliter concentration of those same three plates is 17.0 millimeters, the corrected value is then 17.2 millimeters.

Plot these corrected values, including the average of the 20 micrograms per milliliter concentration on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points.

To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 20 micrograms per milliliter unit zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the micrograms per milliliter unit value on the curve. From the curves read the potencies corresponding to these corrected values of zone sizes.

(8) *Turbidimetric assay.* In lieu of the plate assay method described above, the sample may be assayed for potency by the following turbidimetric method:

(i) *Test culture and media.* Employ the agar described in paragraph (b), § 141.1 for maintaining the test organism which is M. pyogenes var. aureus (P. C. I. 209–P and American Type Culture Collection 6538–P). Transfer the organism to fresh agar slants and incubate at 32° C.–35° C. overnight. For use in the assay, suspend daily the growth from a fresh slant in a small amount of nutrient broth prepared as in § 141.1 (b) (3) and transfer to a flask containing sufficient nutrient broth warmed to 32° C.–35° C. (about 150 milliliters) to give a light transmission reading of 85 percent using a filter at 6,500 Angstrom units in a photoelectric colorimeter. Prepare the daily inoculum by adding 40 milliliters of this suspension to each liter of nutrient broth needed for the test.

(ii) *Working standard and solutions.* Prepare a standard stock solution as described in subparagraph (3) of this paragraph, or dissolve a weighed portion of working standard in M/10 monopotassium phosphate buffer pH 4.5 to contain 10 micrograms per milliliter. Small aliquots, each sufficient for a day's test, if kept frozen, may be used for at least two months.

To prepare solutions for the standard curve, make further dilutions of the stock solution to contain 0.1 microgram and 0.2 microgram per milliliter respectively in phosphate buffer solution. To a triplicate series of 18 x 105 millimeter tubes add 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, and 1.0 milliliter respectively of the 0.1 microgram per milliliter solution, and to another triplicate series of tubes add 0.1, 0.2, 0.3, 0.4, and 0.5 milliliter, respectively, of the 0.2 microgram per milliliter solution. Adjust volumes of all tubes to 1.0 milliliter with buffer solution.

To prepare solutions for use in adjusting the photoelectric colorimeter, dilute the stock solution of the working standard to 1.0 microgram per milliliter and add 1.0 milliliter of this solution to each of 10 tubes. To another series of 10 tubes add 1.0 milliliter of the M/10 monopotassium phosphate buffer, pH 4.5.

To each of all the above tubes add 9.0 milliliters of inoculated broth described in subdivision (i) of this subparagraph and place immediately in a water bath

at 32° C.–35° C. for 3½ hours. Then add 0.5 milliliter of formalin diluted 1:3 to each tube.

(iii) *Preparation of sample.* Dilute sample under test with M/10 monopotassium phosphate buffer pH 4.5 to contain 0.06 microgram per milliliter (estimated). (The stock solution may be prepared in distilled water.) Add 1.0 milliliter of this dilution to each of three 18 x 150 millimeter tubes. Add 9.0 milliliters of inoculated broth described in subdivision (i) of this subparagraph to each tube and place immediately in a 32° C.–35° C. water bath for 3½ hours. After incubation add 0.5 milliliter of formalin diluted 1:3 to each tube and read the percent light transmission in a photoelectric colorimeter, using a broad band filter having a light transmission of 5,800 Angstrom units.

(iv) *Estimation of potency.* Average the light transmission readings for each concentration of the standard. Plot these values on cross-section paper using average light transmission readings as the ordinate and aureomycin concentrations in micrograms per tube as the abscissa. Prepare the standard curve by connecting successive points with a straight edge. Since the final concentration of aureomycin per milliliter of broth is equivalent to the concentration per milliliter of the standard solution used, the latter concentrations for each concentration level of the standard may be expressed as percent and substituted on the abscissa of the standard curve. Thus the 0.06 microgram concentration is 100 percent, the 0.05 microgram concentration 83.3 percent, etc. If this is done the percent potency of the sample under test may be read directly from the standard curve.

(9) *Colorimetric assay.* In lieu of the assay methods described above, the sample may be assayed by the following colorimetric method: Prepare an aqueous solution of 0.5 milligram per milliliter of the sample to be assayed. Transfer two 2.0-milliliter aliquots to each of two 50-milliliter volumetric flasks. Add 5.0 milliliters of 2 N HCl to one flask and 5.0 milliliters of distilled water to the other flask as a control blank. Heat both flasks in a boiling water bath for 5 minutes, then cool the flasks under tap water, add 5.0 milliliters of 2 N HCl to the control blank and immediately make up to mark with distilled water. Transfer the solutions to 1.0-cm. colorimetric cells, set the photoelectric colorimeter at 100 percent light transmission for the blank, using a 440-mμ filter. Then replace this with the cell containing the unknown and read the percent transmission. Determine the concentration of the unknown solution by reference to a standard curve prepared by treating appropriate aliquots of a standard solution of pure aureomycin hydrochloride as described above.

(10) The potency of aureomycin is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 85 percent of the number of grams they are represented to contain.

(b) *Sterility.* Proceed as directed in § 141.108 (c).

(c) *Toxicity.* Proceed as directed in § 141.4, using as a test dose 0.5 ml. of an aqueous solution containing 2 milligrams per milliliter.

(d) *Pyrogens.* Proceed as directed in § 141.3, using as a test dose 1.0 ml. per kilogram of an aqueous solution containing 5 mg. per milliliter.

(e) *Histamine.* Proceed as directed in § 141.105, using as a test dose 0.6 ml. of a solution containing 5 mg. per milliliter prepared with the diluent recommended by the manufacturer in his labeling for the drug.

(f) *Moisture.* Proceed as directed in § 141.5 (a) or § 141.26 (e).

(g) *pH.* Proceed as directed in § 141.5 (b), using a saturated aqueous solution.

(h) *Microscopical test for crystallinity.* Proceed as directed in § 141.5 (c).

§ 141.202 *Aureomycin ointment*—(a) *Potency.* Proceed as directed in § 141.201 (a), except subparagraph (10) thereof, and in lieu of the directions in subparagraphs (4) and (8) (iii) of § 141.201 (a) prepare the sample as follows: Accurately weigh the container and contents and place 0.5 to 1.0 gm. into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Reweigh the container to obtain weight of ointment used in the test. Shake ointment and ether until homogeneous. Shake with a 25-milliliter portion of the buffer solution. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine the extracts and make the proper estimated dilutions in the buffer solution. The potency of aureomycin ointment is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.8 (b).

§ 141.203 *Aureomycin troches*—(a) *Potency.* Proceed as directed in § 141.201 (a) except subparagraph (10) thereof, and in lieu of the directions in subparagraphs (4) and (8) (iii) of § 141.201 (a) prepare the sample as follows: Place 12 troches in a glass blending jar containing 500 milliliters of sterile distilled water. Using a high-speed blender, blend for 3 to 5 minutes and then make the proper estimated dilutions in the buffer solution. The average potency of the troches is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.204 *Aureomycin capsules*—(a) *Potency.* Proceed as directed in § 141.203 (a), using one capsule of 250 mg. or five capsules of 50 mg. for the sample and 500 ml. of water in the blender. The average potency of the capsules is satisfactory if it contains not less than 85% of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a) or § 141.26 (e).

§ 141.205 *Aureomycin powder*—(a) *Potency.* Proceed as directed in § 141.203 (a), using 3 gm. of sample. The average potency of the powder is satisfactory if it contains not less than 85% of the number of milligrams of aureomycin per gram it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.206 *Aureomycin ophthalmic*—(a) *Potency.* Proceed as directed in § 141.201 (a).

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.207 *Aureomycin tablets*—(a) *Potency.* Proceed as directed in § 141.204 (a), using 5 tablets of 50 mg. each or the equivalent. The average potency of the tablets is satisfactory if it contains not less than 85% of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a) or § 141.26 (e).

§ 141.208 *Aureomycin otic*—(a) *Potency.* Proceed as directed in § 141.201 (a).

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.209 *Aureomycin dental cones*—(a) *Potency.* Proceed as directed in § 141.203 (a), using 500 ml. of distilled water to prepare the sample. The average potency of the cone is satisfactory if it contains not less than 85% of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.210 *Aureomycin dental paste*—(a) *Potency.* Proceed as directed in § 141.203 (a), using an accurately weighed sample of approximately 2.0 grams and blend in 200 cubic centimeters of sterile distilled water. The potency of aureomycin dental paste is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.8 (b).

§ 141.301 *Chloramphenicol*—(a) *Potency*—(1) *Cylinders (cups).* Use cylinders described under § 141.1 (a).

(2) *Culture media.* Use the medium described under § 141.1 (b) (1) for both the seed layer and the base layer. Use the nutrient broth described under § 141.1 (b) (3) for preparing a suspension of the test organism.

(3) *Working standard.* Prepare the working standard by weighing out carefully appropriate amounts of the chloramphenicol working standard and dilute in 1% phosphate buffer pH 6.0 to give a solution containing 50 micrograms per milliliter. Keep this stock solution at a temperature of 15° C. or less and use for only 1 month. The standard may first be dissolved in a small amount of ethyl alcohol to facilitate solution.

(4) *Preparation of sample.* Prepare the sample to be tested by dissolving in a small amount of ethyl alcohol and then further dilute in 1% phosphate buffer pH 6.0 to make an appropriate stock solution.

(5) *Preparation of suspension.* The test organism is Sarcina lutea (P. C. I. 1001). Maintain the test organism on slants of nutrient agar prepared as in subparagraph (2) of this paragraph and transfer to a fresh agar slant once a

week. Prepare a suspension of the test organism as follows: Streak an agar slant heavily with the test organism. Wash the growth off in about 3 ml. of nutrient broth. Use the suspension so obtained to inoculate the surface of a Roux bottle containing 300 ml. of the nutrient agar. Spread the suspension over the entire surface with the aid of sterile glass beads. Incubate for 24 hours at 26° C. Wash the growth from the agar surface with 20 ml. of nutrient broth prepared as in subparagraph (2) of this paragraph. If an aliquot of this bulk suspension, when diluted with nutrient broth 1:10, gives a 10% light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6500 Angstrom units, it is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:10 give 10% light transmission. (The adjusted bulk suspension only, and not the 1:10 dilution of it, is used in preparing the seed layer.) The bulk suspension may be used in the test for 1 month. Add 1 to 1.5 ml. of the adjusted bulk suspension to 100 ml. of agar which has been melted and cooled to 48° C.

(6) *Preparation of plates.* Add 21 ml. of the agar prepared as in subparagraph (2) of this paragraph to each Petri dish (20 x 100 mm.). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. Add 4 ml. of the inoculum prepared as in subparagraph (5) of this paragraph for each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(7) *Assay.* Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-cm. radius. Use three plates for each sample. Fill three cylinders on each plate with the 50 micrograms per milliliter standard and three cylinders with the 50 micrograms per milliliter (estimated) sample, alternating standard and sample. At the same time prepare a standard curve, using concentrations of the standard of 30.0, 35.0, 40.0, 45.0, 50.0, 55.0, 60.0, 65.0, and 70.0 micrograms per milliliter. A total of 24 plates is used in the preparation of the standard curve, three plates for each solution except the 50 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill three cylinders with the 50 micrograms per milliliter standard and the other three cylinders with the concentration of the standard under test. Thus, there will be seventy-two 50 micrograms determinations and nine determinations for each of the other points on the curve. Incubate the plates for 16 to 18 hours at 32° C.–35° C. and measure the diameter of each circle of inhibition. Average the readings of the 50 micrograms per milliliter concentration and the readings of the point tested for each set of three plates, and average also all 72 readings of the 50 micrograms per milliliter concentration. The average of the 72 readings of the 50 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 50 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 40 micrograms per milliliter concentration the average of the 72 readings of the 50 micrograms per milliliter is 18.0 mm., and the average of the 50 micrograms per milliliter concentration of this set of three plates is 17.8 mm., the correction is 0.2 mm. If the average reading of the 40 micrograms per milliliter concentration of these same three plates is 17.0 mm., the corrected concentration of these same three plates is 17.0 mm., the corrected value is then 17.2 mm.

Plot these corrected values, including the average of the 50 micrograms per milliliter concentrations on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points.

To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 50 micrograms per milliliter unit zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 50 micrograms per milliliter unit value on the curve. From the curves read the potencies corresponding to these corrected values of zone sizes.

(8) *Spectrophotometric method.* In lieu of the plate-assay method described above, the following method may be used:

Dissolve 20 mg. of the sample, accurately weighed, in 100 ml. of distilled water, warming to hasten solution. Cool to room temperature, dilute to exactly 1,000 ml. with distilled water, and mix. With a suitable spectrophotometer determine the optical density of the solution in a 1-cm. cell at 278 mμ compared with distilled water as a blank. Multiply the optical density figure obtained by the appropriate factor to obtain the optical density value of a 1% solution. The $E^{1\%}_{1\ cm.}$ value of the sample multiplied by 100, divided by 298 represents the percent potency.

(9) The potency of chloramphenicol is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 85% of the number of grams they are represented to contain.

(b) *Sterility.* Proceed as directed in § 141.108 (c).

(c) *Toxicity.* Proceed as directed in § 141.4, using as a test dose 0.5 ml. of a solution containing 2 mg. per milliliter. Use physiological salt solution as the diluent.

(d) *Pyrogens.* Proceed as directed in § 141.3, using as a test dose 1.0 ml. per kilogram of a solution containing 5 mg. per milliliter. Use physiological salt solution as the diluent.

(e) *Histamine.* Proceed as directed in § 141.105, using as a test dose 0.6 ml. of a solution containing 5 mg. per milliliter prepared by application of heat.

(f) *pH.* Proceed as directed in § 141.5 (b) using a saturated aqueous solution.

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141.5 (c).

(h) *Specific rotation.* Accurately weigh approximately 1.25 gm. of the sample in a 25-ml. glass-stoppered volumetric flask and dissolve in about 15 ml. of absolute alcohol, warming if necessary. Dilute the solution to 25 ml. with absolute alcohol and mix thoroughly. Transfer the solution to a 200-mm. tube, determine the angular rotation in a suitable polarimeter, using sodium light or a 5893 Angstrum filter, and calculate the specific rotation.

(i) *Melting point.* Proceed as directed by the U. S. P.

(j) *Extinction coefficient.* Proceed as directed in paragraph (a) (8) of this section.

§ 141.302 *Chloramphenicol capsules*— (a) *Potency.* (1) Proceed as directed in § 141.301 (a), except subparagraph (9) of § 141.301 (a), and in lieu of the directions in subparagraph (4) of § 141.301 (a) prepare sample as follows: Place the contents of one capsule and the empty capsule in a 250-ml. volumetric flask. Add 50 ml. of ethyl alcohol, shake well, and make to 250 ml. with 1% phosphate buffer pH 6.0. Shake the flask well. Withdraw a 1-ml. aliquot and make the proper estimated dilutions in 1% phosphate buffer at pH 6.0.

(2) The potency may also be determined as directed in § 141.301 (a) (8), except prepare the sample as follows: Rinse the contents of one capsule into a liter volumetric flask using about 250 ml. of water. Warm the contents of the flask gently until complete solution is obtained, cool and make up to volume. Dilute a 4-ml. aliquot of this solution to exactly 50 ml. for the assay.

(3) The potency of the capsule is satisfactory if it contains not less than 85% of the number of milligrams it is represented to contain.

§ 141.401 *Bacitracin* — (a) *Potency.* (1) *Plate assay.* Proceed as directed in § 141.101, with the following exceptions:

(i) Use the culture media for the seed layer and the base layer as described in § 141.1 (b) (1) and (2).

(ii) Use the bacitracin working standard and dissolve in 1% phosphate buffer to make an appropriate stock solution. The stock solution when refrigerated may be used for 2 weeks. The stock solution may also be preserved for at least 2 months by freezing in small aliquots. Each aliquot should be sufficient for 1 day's use only. Make all dilutions of the stock solution for the assay with 1% phosphate buffer.

(iii) Dissolve the sample to be tested in 1% phosphate buffer and make dilutions with the same solvent to one unit per milliliter (estimated).

(iv) The test organism is *Micrococcus flavus*, which is maintained at refrigerator temperature on slants of nutrient agar prepared as directed in § 141.1 (b) (2). Inoculate a Roux bottle containing agar from a stock slant of the organism and incubate 18 hours at 32° C.–35° C. Wash off the growth in 25 ml. of sterile

physiological saline solution. If an aliquot of this bulk suspension, when diluted 1:50 in physiological saline solution, gives 75% light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6500 Angstrom units, the bulk suspension is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:50 gives 75% light transmission. (The adjusted bulk suspension only, and not the 1:50 dilution of it, is used in preparing the seed layer.) Add 0.3 to 0.5 ml. of the adjusted bulk suspension to 100 ml. of agar which has been melted and cooled to 48° C.

(2) *Turbidimetric assay.* In lieu of the plate-assay method described above, the sample may be assayed for potency by the following turbidimetric method:

(i) Employ the agar described in § 141.1 (b) (2) (adjusted to a final pH 7.0) for maintaining the test organism, which is Staphylococcus aureus (PCI 1203). Transfer stock cultures every 2 weeks for test purposes. On the day of test transfer the growth from a stock slant to approximately 100 ml. of nutrient broth (§ 141.1 (b) (3)). Incubate the inoculated broth until the culture has grown sufficiently to give a light transmission reading of 80–90%, using a filter having a light transmission peak at 6500 Angstrom units. This culture may be held overnight at refrigerator temperature if desired. Prepare the "daily" inoculum by adding approximately 6.0 ml. of the standardized broth culture to each 100 ml. of broth previously cooled to a temperature of approximately 15° C.

(ii) *Working-standard solutions.* Dilute the working standard to 10 units per milliliter of bacitracin in 1% phosphate buffer. Further dilute this to make solutions containing 0.100, 0.141, 0.200, 0.282, 0.398, and 0.562 units per milliliter. These solutions are used for preparing the standard curve and may be held at 15° C. for 1 week. Add 1.0 ml. of each of these working solutions to each of six 14 x 124 mm. test tubes (sextuplicate).

(iii) *Preparation of sample.* Dilute the sample under test to 0.25 unit per milliliter (estimated). Add 1.0 ml. of diluted sample to each of six 14 x 124 mm. test tubes (sextuplicate). Add 9.0 ml. of the "daily" inoculum described above to each tube of the standard and unknown series and place immediately in a 32° C.–35° C. water bath for 4 hours. After incubation, add four drops of formalin to each tube, and estimate the turbidity of each in a photoelectric colorimeter, using a broad-band filter having a wave length of 5300 Angstrom units.

(iv) *Estimation of potency.* Average the six colorimeter readings at each standard level. Plot the average turbidity figures of the standard on semilog graph paper, employing units per tube as the abscissa (log scale) and light transmission as the ordinate. Connect the points with a straightedge. Average the sample readings and read in units per tube from the curve. Units per tube multiplied by 100 will give percent potency of the sample.

(3) The potency of the bacitracin is satisfactory when assayed by the methods described in this section if the immediate containers contain 85% of the number of units they are represented to contain.

(b) *Sterility*—(1) *Culture medium.* Prepare fluid thioglycollate medium as described in § 141.2 (a).

(2) *Conduct of test.* Add aseptically to each of two tubes containing approximately 15 ml. of fluid thioglycollate medium, 1.0 ml. of a 500 units per milliliter dilution in sterile distilled water of the bacitracin under test. Add 0.1 ml. of the 500 units per milliliter dilution to two additional tubes of thioglycollate medium. Incubate at 32° C.–35° C. for 4 days. If no tube shows growth the sample is satisfactory. This method will demonstrate only those organisms which are not susceptible to this concentration of bacitracin.

(c) *Pyrogens.* Proceed as directed in § 141.3, using as a test dose 1.0 ml. per kilogram of a solution containing 300 units per milliliter. Use physiological salt solution as the diluent.

(d) *Toxicity.* Prepare solutions of the sample under test containing 200, 400, 600, 800, and 1,000 units per milliliter, using sterile physiological salt solution. Inject intravenously each of ten mice within the weight range of 18–25 gm. with 100, 200, 300, 400, and 500 units per 20 gm., respectively, utilizing the above solutions. The injections must be made over a period of not more than 5 seconds. Determine the $L. D._{50}$, utilizing all mice injected, by plotting on semilogarithmic paper the percent of deaths after 72 hours on the ordinate against dosage per 20-gm. mouse on the abscissa (logarithmic scale). The $L. D._{50}$ shall be not less than 200 units per 20-gm. mouse.

(e) *Moisture.* Proceed as directed in § 141.5 (a).

(f) *pH.* Proceed as directed in § 141.5 (b), using a solution containing 10,000 units per milliliter.

§ 141.402 *Bacitracin ointment.*—(a) *Potency.* Proceed as directed in § 141.401 (a), except subparagraph (3) thereof, and in lieu of the directions in subparagraph (1) (iii) of § 141.401 (a) prepare the sample as directed to § 141.8 (a). The potency of bacitracin ointment is satisfactory if it contains not less than 85% of the number of units per gram it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.8 (b).

§ 141.403 *Bacitracin tablets*—(a) *Potency.* Proceed as directed in § 141.401 (a), except subparagraph (3) thereof, and in lieu of the directions in subparagraph (1) (iii) of § 141.401 (a), prepare sample as directed in § 141.9 (a). The average potency of bacitracin tablets is satisfactory if it contains not less than 85% of the number of units per tablet it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.404 *Bacitracin troches*—(a) *Potency.* Proceed as directed in § 141.403 (a). The average potency of bacitracin troches is satisfactory if it contains not less than 85% of the number of units per troche it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.405 *Bacitracin with vasoconstrictor*—(a) *Potency.* Proceed as directed in § 141.401 (a), except subparagraph (3) thereof. The potency of bacitracin with vasoconstrictor is satisfactory if it contains not less than 85% of the number of units per container it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

§ 141.406 *Bacitracin - tyrothricin troches*—(a) *Potency.* Proceed as directed in § 141.403 (a). Its content of bacitracin is satisfactory if it contains not less than 85% of the number of units per troche it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141.5 (a).

PART 146—CERTIFICATION OF BATCHES OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

Sec.

Sec.

§ 146.1 *Definitions and interpretations.* For the purpose of the regulations in this part:

(a) Each of the several antibiotic substances (e. g. penicillin F, penicillin G, penicillin X) produced by the growth of Penicillium notatum or Penicillium chrysogenum, and each of the same substances produced by any other means, is a kind of penicillin.

Wherever the term "penicillin" appears in the regulations in this part it means sodium penicillin, calcium penicillin, or potassium penicillin, or any combination of two or all of these, unless otherwise specified.

(b) Each of the several antibiotic substances produced by the growth of Streptomyces griseus, and each of the same substances produced by any other means, is a kind of streptomycin.

Wherever the term "streptomycin" appears in the regulations in this part it means streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, or streptomycin trihydrochloride calcium chloride, or any combination of two or all of these, unless otherwise specified.

Wherever the term "dihydrostreptomycin" appears in the regulations in this part it means dihydrostreptomycin sulfate, or dihydrostreptomycin hydrochloride, or a combination of these two, unless otherwise specified.

(c) Each of the several antibiotic substances produced by the growth of Streptomyces aureofaciens, and each of the same substances produced by any other means, is a kind of aureomycin.

Wherever the term "aureomycin" appears in the regulations in this part it means aureomycin hydrochloride unless otherwise specified.

(d) Each of the several antibiotic substances produced by the growth of Streptomyces venezuelae, and each of the same substances produced by any other means, is a kind of chloramphenicol.

(e) Each of the several antibiotic substances produced by the growth of Bacillus subtilis var. Tracy, and each of the same substances produced by any other means, is a kind of bacitracin.

(f) The term "penicillin G master standard" means a specific lot of crystalline sodium penicillin G (sodium penicillin II), which is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin G working standards. The term "penicillin O master standard" means a specific lot of crystalline potassium penicillin O which is designated by the Commissioner as the standard of comparison in determining the penicillin O content and the penicillin G content of the penicillin O working standard.

(g) The term "streptomycin master standard" means a specific lot of crystalline trihydrochloride calcium chloride salt of streptomycin which is designated by the Commissioner as the standard of comparison in determining the potency of the streptomycin working standard.

(h) The term "dihydrostreptomycin master standard" means a specific lot of crystalline dihydrostreptomycin sulfate which is designated by the Commissioner as the standard of comparison in determining the potency of the dihydrostreptomycin working standard.

(i) The term "aureomycin master standard" means a specific lot of crystalline aureomycin hydrochloride which is designated by the Commissioner as the standard of comparison in determining the potency of the aureomycin working standard.

(j) The term "chloramphenicol master standard" means a specific lot of crystalline chloramphenicol which is designated by the Commissioner as the standard of comparison in determining the potency of the chloramphenicol working standard.

(k) The term "bacitracin master standard" means a specific lot of bacitracin which is designated by the Commissioner as the standard of comparison in determining the potency of the bacitracin working standard.

(l) The term "unit" applied to penicillin means a penicillin activity contained in 0.6 microgram of the penicillin master standard; the term "penicillin potency" means the number of such units in a specified quantity of a substance. The term "unit" applied to bacitracin means a bacitracin activity contained in 23.8 micrograms of the bacitracin master standard after it is dried for 3 hours at 60° C. and a pressure of 5 mm. or less; the term "bacitracin potency" means the number of such units in a specified quantity of a substance.

(m) The term "microgram" applied to streptomycin means the streptomycin activity (potency) contained in 1.38 micrograms of the streptomycin master standard after it is dried for 4 hours at 56° C. and a pressure of 50 microns or less. The term "microgram" applied to dihydrostreptomycin means the dihydrostreptomycin activity (potency) contained in 1.25 micrograms of the dihydrostreptomycin master standard after it is dried for 4 hours at 100° C. and a pressure of 50 microns or less. The term "microgram" applied to aureomycin means the aureomycin activity (potency) contained in 1.0 microgram of the aureomycin master standard. The term "microgram" applied to chloramphenicol means the chloramphenicol activity (potency) contained in 1.0 microgram of the chloramphenicol master standard.

(n) The term "penicillin G working standard" means a specific lot of a homogeneous preparation of one or more salts of penicillin G; the term "penicillin O working standard" means a specific lot of a homogeneous preparation of potassium penicillin O; the term "streptomycin working standard" means a specific lot of a homogeneous preparation of one or more streptomycin salts; the term "dihydrostreptomycin working standard" means a specific lot of a homogeneous preparation of one or more dihydrostreptomycin salts; the term "aureomycin working standard" means a specific lot of a homogeneous preparation of one or more aureomycin salts; the term "chloramphenicol working standard" means a specific lot of a homogeneous preparation of one or more chloramphenicols; the term "bacitracin working standard" means a specific lot of a homogeneous preparation of one or more bacitracins. The potency or purity of each preparation has been determined by comparison with its master standard, and each has been designated by the Commissioner as working standards for use in determining the potency or purity of drugs subject to the regulations in this part.

(o) The term "batch" means a specific homogeneous quantity of a drug.

(p) The term "batch mark" means an identifying mark or other identifying device assigned to a batch by the manufacturer or packer thereof.

(q) The term "Commissioner" means the Commissioner of Food and Drugs and any other officer of the Food and Drug Administration whom he may designate to act in his behalf for the purposes of the regulations in this part.

(r) The term "U. S. P." means the official Pharmacopoeia of the United States, including supplements thereto. The term "N. F." means the official National Formulary, including supplements thereto.

(s) The term "manufacture" does not include the use of a drug as an ingredient in compounding any prescription issued

in his professional practice by a physician, dentist, or veterinarian licensed by law to administer or apply such drug.

(t) All statements, samples, and other information and materials submitted in connection with a request for certification shall be considered to be a part of such request.

(u) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this part.

(v) Except as specifically provided by §§ 146.8 to 146.23, inclusive, no provision of any section in this part shall be construed as exempting any drug from any applicable provision of the act or other regulation thereunder.

(w) The regulations in Part 141 of this chapter prescribing tests and methods of assays shall not be construed as preventing the Commissioner from using any other test or method of assay in his investigations to determine whether or not:

(1) A request for certification contains any untrue statement of a material fact; or

(2) A certification has been obtained through fraud, or through misrepresentation or concealment of a material fact.

§ 146.2 *Requests for working standards and certification; information and samples required.* (a) A request for certification of a batch shall be addressed to the Commissioner and shall be in a form specified by him. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) The initial request for certification of a batch of any drug submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of (1) the methods and processes used in the manufacture of the drug; (2) the tests and assays of the drug made during the manufacture of the batch and after it is packaged; and (3) the laboratory facilities used in such controls.

Such initial request shall also be preceded or accompanied by the key of the batch marks used by such person and by specimens of all labeling (including specimens of all brochures and other printed matter except readily available medical publications, referred to in such labeling) to be used for such drug. When any change is made in any such facility or control, or in any such key or labeling, such person shall promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes.

(c) Each sample submitted pursuant to the regulations in this part shall be addressed to the Commissioner. Its package shall be clearly identified as to its contents and shall bear the name and post-office address of the person submitting it.

(d) In addition to the information and samples specifically required to be submitted to the Commissioner by the regulations in this part, the person who requests certification of a batch shall submit such further information and samples as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate.

(e) Upon the request of any person, stating reasonable grounds therefor, the Commissioner shall furnish such person with a portion of the working standards.

§ 146.3 *Certification.* (a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and samples required by or pursuant to the regulations in this part have been submitted, and the request for certification contains no untrue statement of a material fact; and

(2) The batch complies with the regulations in this part and conforms to the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this part; the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of certificates as are prescribed by § 146.4, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to the regulations in this part, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) Compliance of a drug with the standards of identity, strength, quality, and purity prescribed by regulations in this part shall be determined by the tests and methods of assay prescribed for such drug by regulations in Part 141 of this chapter.

§ 146.4 *Conditions on the effectiveness of certificates.* (a) A certificate shall not become effective:

(1) If it is obtained through fraud or through misrepresentation or concealment of a material fact;

(2) With respect to any package unless it complies with the packaging requirements, if any, prescribed by the regulations in this part which were in effect on the date of the certificate;

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this part; or

(4) With respect to any package of penicillin, streptomycin, dihydrostreptomycin, aureomycin, chloramphenicol, or bacitracin, when it is included in a packaged combination with another drug, unless such other drug complies with the requirements of the regulations in this part.

(b) A certificate shall cease to be effective:

(1) With respect to any immediate container after the expiration date, if any, prescribed by the regulations in this part;

(2) With respect to any immediate container when it or its seal (if the regulations in this part require it to be sealed) is broken, or when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this part, except that:

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued in his professional practice by a physician, dentist, or veterinarian licensed by law to administer or apply drugs, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription; or

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by § 146.18;

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with aluminum hydroxide gel or penicillin with a vasoconstrictor, or to any immediate container of bacitracin when it is included in the packaged combination bacitracin with a vasoconstrictor, except that when certification of the batch so included is requested, such certificate shall continue to be effective for a reasonable time to permit certification of such batch which is part of such combination;

(4) With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate; except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded;

(5) With respect to any package of penicillin, streptomycin, dihydrostreptomycin, aureomycin, chloramphenical, or bacitracin, included in a packaged combination with another drug, when such other drug fails to meet the requirements of the regulations in this part; or

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By a physician, dentist, or veterinarian, in his professional practice, who is licensed by law to administer drugs; or

(ii) On his prescription issued in his professional practice.

§ 146.5 *Records of distribution.* (a) The person who requested certification shall keep complete records showing each shipment and other delivery (including

exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than three years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Administrator, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 146.6 *Authority to refuse certification service.* When the Administrator finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by § 146.5; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 146.5, and such failure may materially impair the certification service; the Administrator will immediately suspend service to such person under the regulations in this part and will continue such suspension unless and until such person shows adequate cause why such service should be resumed.

§ 146.7 *New antibiotic and antibiotic-containing products.* Any request that the Administrator provides for the certification of batches of a drug for which no provision for certification is made in the existing regulations in this part shall be in a form specified by the Commissioner and shall be accompanied by:

(a) A statement of the conditions for which the person who makes such request intends such drug to be used, and adequate directions for use in each such condition;

(b) Full reports of investigations which have been made to show whether or not such drug is safe and efficacious for use in such conditions;

(c) A full list of the articles used as components of such drug;

(d) A full statement of the composition of such drug;

(e) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(f) A full description of, or references to publications containing practical and accurate tests and methods of assay to determine the identity, strength, quality, and purity of such drug;

(g) Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and

(h) Specimens of all labeling (including all brochures and other printed matter, except readily available medical publications, referred to in such labeling) proposed to be used for such drug.

§ 146.8 *Fees.* (a) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fee for such services with respect to each batch of a drug, certification of which is provided by the regulations in this part, is the fee prescribed in the section relating specifically to such drug, except that, in case of a supplemental request submitted pursuant to the provisions of § 146.18, the fee shall be $2.00.

(c) When the Commissioner considers it necessary to make investigations of a new penicillin, streptomycin, dihydrostreptomycin, aureomycin, chloramphenicol, or bacitracin product, on which a request has been submitted in accordance with § 146.7, the fee for such service shall be the cost thereof. In such case the request shall be followed by an advance deposit in such amount as the Commissioner specifies, and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(d) A person requiring continuing certification services may maintain an advance deposit of the estimated cost of such services for a two-month period. Such deposit shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in the regulations in this part unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(e) The unearned portion of any advance deposit shall be refunded to the depositor upon his application.

(f) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under § 146.18.

(g) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Treasurer of the United States, collectible at par at Washington, D. C. All such deposits and fees shall be forwarded to the Food and Drug Administration, Federal Security Agency, Washington 25, D. C., whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

§ 146.18 *Exemptions for labeling.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be labeled at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirements of section 502 (f) of the act if the labeling of each shipping container bears the batch mark of the drug, the number of units per package, the expiration date, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for labeling in such establishment.

(b) (1) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.23; that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt, or if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(3) In case the applicant is not the operator of such establishment such application shall include or be accompanied by:

(i) A written agreement signed by the applicant that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.23; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery; and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery; and

(ii) A written agreement signed by the operator of such establishment that he will submit a request, supplemental to that of the applicant, for the certification of each batch or portion thereof comprised in any such shipment or delivery received by him unless it is exempt under section 801 (d) of the act or § 146.23; that he will specify in his request the number of packages of each size in such shipment or delivery, the date of delivery, the batch mark thereof, and the batch mark he will use therefor;

that the batch marks to be used (if different from those of the applicant) will be only those of which the key is specified in this agreement that the expiration date used for the batch will be only that assigned to the manufacturer by certification; that the labeling to be used for such packages will be only that of which specimens are attached to this agreement (including specimens of all brochures and other printed matter, except readily available medical publications, referred to in such labeling); that when any change is made in such key or labeling he will promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes; that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records of the disposition of each such shipment and delivery; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(4) When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.19 *Exemptions for storage.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be stored at a warehouse located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such warehouse, from the requirements of section 502 (l) of the act if the labeling of each shipping container bears the batch mark of the drug, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for storage in such warehouse.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the warehouse in which such drug is to be stored. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, that he will not remove any of such drug from such warehouse unless it complies with section 502 (l) of the act or is so exempt or, if certification is refused unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such warehouse, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery; and

(2) A written statement signed by the operator of such warehouse showing that he has adequate facilities for such storage; such statement shall contain an agreement that he will hold each shipment or other delivery of such drug intact, under such conditions as will not cause failure of the drug to comply with the requirements for certification, that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

If the applicant keeps complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug from such warehouse and the name and post-office address of the person to whom such shipment or delivery was made, the agreement to keep records of such disposals, to make such records available, and to afford opportunity for checking their correctness may be included in the applicant's agreement and omitted from that of the operator.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such warehouse, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such warehouse, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed, or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.20 *Exemptions for processing.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of penicillin, streptomycin, dihydrostreptomycin, aureomycin, chloramphenicol, or bacitracin in concentrated aqueous solution which is to be processed at an establishment located elsewhere than at the place of manufacture shall be exempt during the time of introduction into and movement in interstate commerce and the time of holding in such establishment from the requirements of section 502 (l) of the act, if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for processing in such establishment, and each package of such solution bears the batch mark of the drug.

(b) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such processing is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, potency,

and batch mark of each shipment and other delivery of any such solution to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such processing; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the processing is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23 or, if certification is refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23, or, if certification has been refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

§ 146.21 *Exemptions for repacking.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be repacked at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment from the requirements of section 502 (l) of the act if the labeling of each container bears the batch mark of the drug and the number of units per package, and if the person who introduces such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for repacking in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such repacking is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of each shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such repacking; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the repacking is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt or is returned to him for labeling or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.22 *Exemptions for manufacturing use.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of penicillin, streptomycin, dihydrostreptomycin, aureomycin, chloramphenicol, or bacitracin which is packed in containers of not less than 10,000,000 units of penicillin or 10 grams of streptomycin, dihydrostreptomycin, aureomycin, chloramphenicol, or bacitracin each shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in the establishment where it is so used, from the requirements of section 502 (l) of the act, if it conforms to the standards prescribed therefor by the section of the regulations in this part which is specifically applicable to such other drug, if the label of each container bears the batch mark of the drug, the number of units or grams per package, and the date on which the latest assay of the drug was completed, and if the person who introduced each shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for manufacturing use in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, shall give the name and location of the establishment in which such drug is to be used and shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or em-

ployee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipments or delivery:

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for the manufacture of such other drug; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof and showing the quantity and batch mark of each batch of such other drug manufactured by him and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after its manufacture is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt or is returned to him for labeling.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void ab initio at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801 (d) of the act.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801 (d) of the act.

§ 146.23 *Exemptions for investigational use.* (a) A shipment or other delivery of a drug shall be exempt from section 502 (l) of the act if all of the following requirements are complied with:

(1) The label of such drug bears the batch mark and the statement "Caution—Limited by Federal Law to investigational use only."

(2) Such shipment or delivery is made only to, and solely for investigational use by or under the direction of, an expert qualified by scientific training and experience to investigate the safety or efficacy of such drug.

(3) The person who introduced such shipment or delivery into interstate commerce keeps complete records showing the date, quantity, and batch mark of each such shipment and delivery.

(4) Such person, prior to making such shipment or delivery, obtains a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation. Such person shall keep such statement.

(5) Such person makes all documents referred to in subparagraphs (3) and (4) of this paragraph available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery.

(b) An exemption of a shipment or other delivery of a drug under paragraph (a) of this section shall become void ab initio if:

(1) The person who introduced such shipment or delivery into interstate commerce fails to keep any document required to be kept by paragraph (a) of this section; or

(2) Such person fails to make any such document available for inspection as required by paragraph (a) of this section.

(c) An exemption of a shipment or other delivery of a drug under paragraph (a) of this section shall expire upon the use of any part of such shipment or delivery other than in accordance with the signed statement referred to in subparagraph (4) of paragraph (a) of this section.

§ 146.24 *Sodium penicillin (penicillin sodium, penicillin sodium salt), calcium penicillin (penicillin calcium, penicillin calcium salt), crystalline penicillin (crystalline penicillin sodium, crystalline penicillin sodium salt, crystalline penicillin potassium, crystalline penicillin potassium salt, crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, crystalline penicillin O sodium, crystalline penicillin O sodium salt, crystalline penicillin O potassium, crystalline penicillin O potassium salt)*—(a) *Standards of identity, strength, quality, and purity.* Sodium penicillin is the sodium salt of a kind of penicillin, or a mixture of two or more such salts; calcium penicillin is the calcium salt of a kind of penicillin, or a mixture of two or more such salts; crystalline penicillin is the heat-stable crystalline sodium or potassium salt of one or more kinds of penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; crystalline penicillin G is crystalline penicillin which contains not less than 85 percent by weight of the sodium salt or potassium salt of penicillin G; crystalline penicillin O is crystalline penicillin which contains not less than 85 percent by weight of the sodium salt or potassium salt of penicillin O and it contains not more than 0.5 percent by weight of the sodium salt or potassium salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 500 units per milligram, except that if it contains not less than 90% of a salt of penicillin X its potency is not less than 350 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 2.5 percent unless it is crystalline penicillin in which case its moisture content is not more than 1.5 percent;

(6) Its pH in aqueous solution of 5,000 to 10,000 units per milliliter is not less than 5.0 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 100,000 units, 200,000 units, 300,000 units, 500,000 units, 1,000,000 units, 2,000,000 units, 3,000,000 units, 4,000,000 units, or 5,000,000 units, except that when packaged and labeled solely for dental use each such container may contain not less than 10,000 units, and each may be packaged in combination with a container of the solvent, water for injection U. S. P., dextrose injection 5 percent U. S. P. (if not packaged for dental use), or physiological salt solution U. S. P. In case it is packaged and labeled solely for dental use, it may be packaged in combination with a container of an aqueous solution of a suitable local anesthetic.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date _____," the blank being filled in with the date which is 18 months or if it is crystalline penicillin 36 months, after the month during which the batch was certified; and

(iv) The statement "For Manufacturing Use," "For Repacking," or "For Manufacturing Use or Repacking" when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container if it is not crystalline penicillin the statement "Store in refrigerator not

above 15° C. (59° F.)," or "Store below 15° C. (59° F.)."

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparation and strength of solutions for different routes of injection and local application;

(iii) The conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions and if it is crystalline penicillin the statement "Sterile solution may be kept in refrigerator for three days without significant loss of potency," and if it is not crystalline penicillin the statement "Sterile solution may be kept in refrigerator for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G or crystalline penicillin O), crystallinity and heat stability if it is crystalline penicillin, the penicillin G content if it is crystalline penicillin G or crystalline penicillin O, and the penicillin O content if it is crystalline penicillin O. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than six or more than 13 immediate containers, unless:

(i) It is crystalline penicillin, other than crystalline penicillin G, then not less than 8 and not more than 15 immediate containers;

(ii) If it is crystalline penicillin G or crystalline penicillin O, then not less than 10 and not more than 17 immediate containers;

(iii) If it is packaged in containers of less than 100,000 units each for dental use, then not less than 20 and not more than 100 immediate containers if it is not crystalline penicillin, and not less than 40 and not more than 100 immediate containers if it is crystalline penicillin. Such sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing 6, or in the case of crystalline penicillin 10, approximately equal portions of at least 60 milligrams each taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2), (3), and (4) of this section, except if packaged in containers of less than 100,000 units each for dental use, $1.00 for each immediate container; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

(f) *Exemption of crystalline penicillin G from certification.* Crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, shall be exempt from the requirements of sections 502 (l) and 507. No provision of any regulation in this part shall apply to such drug except the standards of identity, strength, quality, and purity specified for its use in the manufacture of another drug.

§ 146.25 *Penicillin in oil and wax* (calcium penicillin in oil and wax, crystalline penicillin in oil and wax)—(a) *Standards of identity, strength, quality, and purity.* Penicillin in oil and wax is a suspension of calcium penicillin or crystalline penicillin in a menstruum of refined peanut oil or sesame oil in which white wax is dispersed. If it is represented to be free-flowing, not less than 50 percent of the total relative weight of the penicillin in the drug consists of penicillin having a particle size of not less than 50 microns in length. Its potency is 100,000 units, 200,000 units, or 300,000 units per milliliter except if it is packaged and labeled solely for udder instillations of cattle its potency is 2,000 units per milliliter. The content of white wax in the menstruum before the addition of the penicillin is not less than 3.0 percent (w/v) if the potency is to be not more than 200,000 units per milliliter, and not less than 4.7 or more than 4.9 percent (w/v) if the potency is to be 300,000 units per milliliter. The moisture content is not more than 1.0 percent. It is sterile. The calcium penicillin or crystalline penicillin used conforms to the requirements of § 146.24 (a), but its potency is not less than 750 units per milligram if it is used in making a product of not more than 200,000 units per milliliter, and not less than 900 units per milligram if it is used in making a product containing 300,000 units per milliliter. The peanut oil, sesame oil, and the white wax used conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* The immediate container of penicillin in oil and wax shall be of colorless transparent glass (if packaged and labeled solely for udder instillations of cattle, it shall be of transparent glass) so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of penicillin in oil and wax in each such container shall be not less than one milliliter and not more than 20 milliliters, unless it is packaged for repacking or is packaged and labeled solely for udder instillations of cattls. Unless it is packaged for repacking each container shall be filled with a volume of penicillin in oil and wax in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(c) *Labeling.* Each package of penicillin in oil and wax shall bear, on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date _____", the blank being filled in, if crystalline penicillin is used, with the date which is 18 months, or if crystalline penicillin is not used, with the date which

is 12 months after the month during which the batch was certified;

(iv) The statement "For intramuscular use only";

(v) If it is represented to be free-flowing, the statements "Do not heat" and "Shake well";

(vi) If it is represented to contain 2,000 units per milliliter, the statement "For udder installations of cattle only"; and

(vii) The name of each oil used in making the batch.

(2) On the circular or other labeling within or attached to the package, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including site of injection;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including sensitization.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin in oil and wax shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the peanut oil or sesame oil and white wax used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, and if it is represented to be free-flowing, the particle size of the penicillin.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 500 packages in the batch, but in no case less than three packages, except if it is represented to be free-flowing in which case not less than four packages, or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; six packages if it is calcium penicillin or 10 packages if it is crystalline penicillin, containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, the peanut oil or sesame oil and white wax used in making the batch; one package of each containing, respectively approximately 250 grams and 25 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin in oil and wax under the regulations in this part shall be:

(1) $4.00 for each package submitted in accordance with paragraph (d) (3) (i), $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fees prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.26 *Penicillin ointment (calcium penicillin ointment, crystalline penicillin ointment, procaine penicillin ointment)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin ointment is calcium penicillin, crystalline penicillin, or procaine penicillin in a suitable and harmless ointment base with or without a suitable anesthetic. Its moisture content is not more than 1.0%. Its potency is not less than 250 units per gram, except if it is packaged and labeled solely for udder instillations of cattle, its potency is not less than 2000 units per gram. The calcium penicillin or crystalline penicillin used conforms to the requirements of § 146.24 (a), except the limitation on penicillin K content, and except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146.44 (a), except subparagraphs (2) and (3) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Penicillin ointment shall be packaged in collapsible tubes, which shall be well-closed containers as defined by the U. S. P., and shall not be larger than the one-eighth-ounce size if such ointment is represented for ophthalmic use and in no case larger than the two-ounce size, except if it is labeled solely for udder instillations of cattle, it may be packaged in immediate containers of transparent glass which meet the test for tight containers as defined by the U. S. P. Each such glass container shall be so sealed that the contents cannot be used without destroying such seal and shall be closed by a substance through which a hypodermic needle may be introduced and withdrawn without destroying its effectiveness. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin ointment shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units per gram of the batch; and

(iii) The statement "Expiration date _____," the blank being filled in with the date which is not more than 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section;

(iv) If it is labeled solely for udder instillations of cattle and is packaged in glass containers, the statements "Not for injection," "For Udder Instillations of Cattle Only," and "Shake Well."

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)," unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature, but in no case shall such statement be required if it is labeled with an expiration date which is 9 months after the month during which the batch was certified;

(ii) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words as the case may be; and

(iii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such ointment; or a reference to a brochure or other printed matter containing such directions and precautions,

and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such ointment, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is crystalline procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin, 10 packages, each containing approximately equal portions of not less than 60 mg. if it is not procaine penicillin, and not less than 300 mg. if it is procaine penicillin, packaged in accordance with the requirements of § 146.24 (b) or § 146.44 (b).

(iii) In case of an initial request for certification, the ingredients used in making the ointment base of the batch; one package of each containing approximately 200 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin ointment under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.27 *Penicillin tablets*—(a) *Standards of identity, strength, quality, and purity.* Penicillin tablets are tablets composed of sodium penicillin, calcium penicillin, potassium penicillin, or procaine penicillin, with or without two or more suitable sulfonamides and with or without the addition of one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 50,000 units, and if it is less than 100,000 units it is "unscored." Its moisture content is not more than 1.0 percent, except if it contains procaine penicillin its moisture content is not more than 2.0 percent. The sodium pencillin, calcium penicillin, or potassium penicillin used conforms to the requirements of § 146.24 (a), except subparagraphs (1), (2), and (4) of that paragraph, but the potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146.44 (a), except subparagraphs (2) and (3) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin tablet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. If the penicillin tablets are freely soluble, each immediate container may be packaged in combination with one immediate container of a suitable and harmless aqueous vehicle with or without two or more suitable sulfonamides.

(c) *Labeling.* Each package of penicillin tablets shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) If the batch contains sulfonamides, the name and quantity of each such sulfonamide used in making the batch;

(iv) If the batch contains buffer substances, the name of each such substance used in making the batch;

(v) If it is a packaged combination of penicillin tablets and a vehicle with or without sulfonamides, a statement giving the method of dissolving the penicillin; and

(vi) The statement "Expiration date ----------," the blank being filled in, if crystalline sodium or potassium penicillin is used without the addition of buffer substances, diluents, binders, lubricants, colorings, or flavorings and each such tablet is enclosed in a foil or plastic film or other container, with the date which is 36 months; or if each such tablet is not enclosed in a foil or plastic film or other container, or if crystalline sodium or potassium penicillin is used, with the addition of buffer substances, diluents, binders, lubricants, colorings, or flavorings with the date which is 24 months; or if procaine penicillin is used with the date which is 18 months; or if crystalline sodium penicillin, potassium penicillin, or procaine penicillin is not used, with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled the statement "Caution: To be dispensed only by or on the prescription of a ------," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words as the case may be; and

(ii) Unless the drug is intended solely for veterinary use and is so labeled a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such tablets; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the label and labeling, if sulfonamides are present, after the name "Penicillin tablets," wherever it appears, the words "with sulfonamides," in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including those from any buffer substance present.

If two or more such immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The penicillin used in making the batch; six packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 mg. if it is not procaine penicillin, and not less than 300 mg. if it is procaine penicillin, packaged in accordance with the requirements of § 146.24 (b) or § 146.44 (b).

(iii) In case of an initial request, each other substance used in making the batch; one package of each, containing approximately 5 gm., and if the batch or any part thereof is to be packaged in combination with an aqueous vehicle, or when any change is made in the composition of such vehicle, five packages of the vehicle included in the combination.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.29 *Penicillin with aluminum hydroxide gel*—(a) *Standards of identity, strength, quality, and purity.* Penicillin with aluminum hydroxide gel is a packaged combination of one immediate container of penicillin and one immediate container of aluminum hydroxide gel. Such penicillin conforms to the standards prescribed therefor by § 146.24 (a), except subparagraphs (1) and (4) of § 146.24 (a), but its potency is not less than 300 units per milligram. Such aluminum hydroxide gel conforms to the standards prescribed therefor by the U. S. P., but contains not more than 50 viable microorganisms per milliliter.

(b) *Packaging.* The immediate container of the penicillin shall conform to the packaging requirements set forth in § 146.24 (b), except that it shall contain not less than 300,000 units and its closure may be one through which a hypodermic needle cannot be introduced. The immediate container of the aluminum hydroxide gel shall be a tight container as defined by the U. S. P.; the quantity therein shall be 30 milliliters for each 100,000 units in the immediate container of penicillin.

(c) *Labeling.* Each package of penicillin with aluminum hydroxide gel shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) The statement "Expiration date _____", the blank being filled in with the date which is 18 months after the month during which the batch was certified, unless it is crystalline penicillin, in which case the blank is filled in with the date which is 36 months after the month during which the batch was certified.

(2) On the immediate container of the penicillin, the statement "Warning—Not for injection," unless it conforms to the standards and packaging requirements prescribed therefor by § 146.24 (a) and (b), except that the immediate container may contain 300,000 units.

(3) On the outside wrapper or container of the package, the statements:

(i) "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or both as the case may be; and

(ii) "Store in refrigerator not above 15° C. (59° F.)", or "Store below 15° C. (59° F.)," unless it is crystalline penicillin in which case the storage statement may be omitted.

(4) On the circular or other labeling within or attached to the package, directions and precautions adequate for the use of such combination, including:

(i) Clinical indications;

(ii) Dosage and administration, including methods of mixing the penicillin with the aluminum hydroxide gel;

(iii) The conditions under which the mixture should be stored, including a reference to its instability when stored under other conditions and the statement "The mixture may be kept in refrigerator for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with requirements of § 146.2, a person who requests certification of a batch of penicillin for inclusion in such combination shall submit with his request a statement showing the batch mark of the penicillin, the number of packages thereof in such batch, the number of units in the immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such combination was completed, and a statement that the aluminum hydroxide gel conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays made by him on an accurately representative sample of the penicillin for potency, sterility, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) If the penicillin has not been certified previously, such person shall submit in connection with his request a sample of the batch consisting of one package for each 5,000 packages in the batch, but in no case less than 6 or more than 13 packages except that in the case of crystalline penicillin other than crystalline penicillin G such sample shall consist of not less than 8 and not more than 15 packages, and in the case of crystalline penicillin G not less than 10 and not more than 17 packages. Such sample shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities pack-

aged during the intervals are approximately equal.

(4) No result referred to in subparagraph (2) of this paragraph is required if such result has been previously submitted.

(e) *Fees.* The fees for the services rendered with respect to each batch of penicillin for inclusion in combination with aluminum hydroxide gel under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) of this section, or $2.00 if no such sample is submitted, and

(2) If the Commissioner considers that investigations, other than examination of such containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.30 *Penicillin troches (sodium penicillin troches, calcium penicillin troches, potassium penicillin troches, procaine penicillin troches, penicillin troches sodium salt, penicillin troches calcium salt, penicillin troches potassium salt, penicillin troches procaine salt)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin troches are troches composed of sodium penicillin, calcium penicillin, potassium penicillin, or procaine penicillin and one or more suitable and harmless diluents, binders, and lubricants, with or without ethyl aminobenzoate or one or more suitable and harmless masticatory substances, colorings, and flavorings. The potency of each troche is not less than 500 units; the moisture content is not more than 1.0 percent, except that if flavorings are omitted and it contains crystalline penicillin in a base of not less than 50 percent gelatin by weight, its moisture content is not more than 2 percent. The sodium penicillin, calcium penicillin, or potassium penicillin used conforms to the requirements of § 146.24 (a) except the limitation on penicillin K content and except subparagraphs (1), (2), and (4) of § 146.24 (a), but the potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146.44 (a), except the limitation on penicillin K content and except subparagraphs (2) and (3) of § 146.44 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each troche of the batch; and

(iii) The statement "Expiration date ----------," the blank being filled in, if crystalline sodium, potassium, or procaine penicillin is used, with the date which is 12 months after the month during which the batch was certified; except if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for 18 months at room temperature such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section, the blank shall be filled in with the date which is 18 months; or if crystalline sodium, potassium, or procaine penicillin is not used, with the date which is 9 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) If crystalline sodium, potassium, or procaine penicillin is not used, the statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(ii) The statement "Caution: To be dispensed only by or on the prescription of a ----," the blank being filled in with the word "physician" or "dentist" or both, as the case may be; and

(iii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such troches; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the label and labeling if a masticatory substance is present, whenever the name penicillin troches appears, the word "chewing" or "masticatory" in juxtaposition with such name.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per troche, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is crystalline procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one troche for each 5,000 troches in the batch, but in no case less than 20 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 mg. if it is not procaine penicillin, and not less than 300 mg. if it is procaine penicillin, packaged in accordance with the requirements of § 146.24 (b) or § 146.44 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch of penicillin troches under the regulations in this part shall be:

(1) $1.00 for each troche without masticatory substance in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $2.00 for each troche with masticatory substance in such sample. $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.31 *Penicillin dental cones (calcium penicillin dental cones, penicillin dental cones calcium salt, crystalline penicillin dental cones)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin dental cones are composed of calcium penicillin or crystalline penicillin and one or more suitable and harmless diluents, binders, and lubricants, with or without one or both of the sulfonamides, sulfanilamide and sulfathiazole. The potency of each cone is not less than 500 units. Its moisture content is not more than 1.0 percent. If a sulfonamide is used its quantity is not less than 0.032 gm. per cone. The penicillin used conforms to the requirements of § 146.24 (a) except the limitation on penicillin K content and except subparagraphs (1), (2), and (4) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each diluent, binder, lubricant, and sulfonamide used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin dental cone is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the cones by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin dental cones shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container;

(i) The batch mark;

(ii) The number of units in each cone of the batch;

(iii) The statement "Expiration date _____", the blank being filled in, if crystalline penicillin is used, with the date which is 18 months, or if crystalline penicillin is not used, with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled the statement "Caution: To be dispensed only by or on the prescription of a ____", the blank being filled in with the words "physician" or "dentist" or "veterinarian" or of any combination of two or all of these words, as the case may be; and

(ii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such cones; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the label and labeling if a sulfonamide is present, after the name penicillin dental cones wherever it appears, the word "with ____" in juxtaposition with such name, the blank being filled in with the name of the sulfonamide used.

(4) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such penicillin dental cones, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin dental cones shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each cone, the quantity of each ingredient used in making the batch, the date on which the latest assay of the cones comprising such batch was completed, and that each binder, diluent, lubricant, and sulfonamide used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(i) The batch; average potency per cone and average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, and heat stability if it is crystalline penicillin and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one cone for each 5,000 cones in the batch; but in no case less than 20 cones or more than 100 cones, collected by taking single cones at such intervals throughout the entire time the cones are being made that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; five packages if it is calcium penicillin or 10 packages if it is crystalline penicillin containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin dental cones under the regulations in this part shall be:

(1) $1.00 for each cone in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such cones and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.32 *Penicillin with vasoconstrictor; penicillin with _____ (the blank being filled in with the common or usual name of the vasoconstrictor)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin with vasoconstrictor is a dry mixture of penicillin and a suitable vasoconstrictor with or without suitable buffer substances and preservatives, or it is a packaged combination of one immediate container of penicillin and one immediate container of an aqueous solution of a suitable vasoconstrictor. The penicillin is of such quantity that when dissolved as directed the potency of such solution is not less than 500 units per milliliter after it has been kept for 7 days at a temperature of 15° C. (59° F.). Such solution is isotonic and has a pH of 6, ±0.2. The moisture content of the dry mixture of penicillin with vasoconstrictor is not more than 1.5 percent. The penicillin used conforms to the requirements of § 146.24 (a), except the limitation on penicillin K content and except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate container of the dry mixture of penicillin with vasoconstrictor may be packaged in combination

with an immediate container of a suitable aqueous diluent.

(c) *Labeling.* Each package of penicillin with vasoconstrictor shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) If it is a packaged combination of one immediate container of penicillin and one immediate container of a vasoconstrictor, the statement "Expiration date _____," the blank being filled in with the date which is 18 months, or if it is crystalline penicillin 36 months, after the month during which the batch was certified. If it is the dry mixture of penicillin with vasoconstrictor, the statement "Expiration date _____," the blank being filled in with the date which is 18 months after the month during which the batch was certified.

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination:

(i) A statement giving the method of dissolving the penicillin, and if it is not a packaged combination, a statement that distilled water U. S. P. should be used;

(ii) The potency per milliliter after the penicillin has been dissolved therein;

(iii) If it is a packaged combination of one immediate container of penicillin and one immediate container of a vasoconstrictor and it is not crystalline penicillin, the statement "Store in refrigerator not above 15° C. (59° F.)."

(iv) The statement "Warning—Not for injection."

(v) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions, and a statement "The solution may be kept in a refrigerator for one week without significant loss of potency."

(3) On the outside wrapper or container, unless it is intended solely for veterinary use and is conspicuously so labeled:

(i) The statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of penicillin with vasoconstrictor; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(4) If intended solely for veterinary use, directions and precautions adequate for the use of such penicillin with vasoconstrictor, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin with vasoconstrictor shall submit with his request a statement showing the batch mark, the number of packages thereof in such batch, the number of units in each immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such batch was completed, the quantity of each ingredient used in making the batch of the dry mixture of penicillin with vasoconstrictor, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The penicillin included in the packaged combination and the penicillin used in making the batch of the dry mixture of penicillin with vasoconstrictor; potency, toxicity, moisture, pH, crystallinity and heat stability, if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(ii) The solution after the penicillin has been dissolved therein; potency.

(iii) The batch of the dry mixture of penicillin with vasoconstrictor; potency, moisture content.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The penicillin for inclusion in the packaged combination of penicillin with vasoconstrictor; one immediate container or tablet for each 5,000 immediate containers or tablets in the batch, but in no case less than 20 immediate containers or tablets and not more than 100 immediate containers or tablets, if the penicillin used has been previously submitted, and not less than 40 immediate containers or tablets and not more than 100 immediate containers or tablets if the penicillin used has not been previously submitted, collected by taking single immediate containers or tablets at such intervals throughout the entire time of packaging or tableting the batch that the quantities packaged or tableted during the intervals are approximately equal.

(ii) The dry mixture of penicillin with vasoconstrictor; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 20 immediate containers and not more than 100 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal;

(iii) The penicillin used in making the batch of the dry mixture of penicillin with vasoconstrictor; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146.24 (b);

(iv) In case of an initial request for certification of a batch of a dry mixture of penicillin with vasoconstrictor, each other substance used in making the batch; one package of each containing approximately 5 grams;

(v) In case of an initial request for certification of the packaged combination of penicillin with vasoconstrictor, or when any change is made in the composition of such solution; five packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (i) of this paragraph, and no samples referred to in subparagraph (3) (i) and (iii) of this paragraph are required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin with vasoconstrictor under the regulations in this part shall be:

(1) $1.00 for each immediate container or tablets submitted in accordance with paragraph (d) (3) (i) and (ii) of this section, or $2.00 if no such sample is submitted; $4.00 for each package submitted in accordance with paragraph (d) (3) (iii), (iv), and (v) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.33 *Penicillin for surface application*—(a) *Standards of identity, strength, quality, and purity.* Penicillin for surface application is calcium penicillin and one or more of the diluents sodium chloride, milk sugar, sodium citrate, and dextrose. Its moisture content is not more than 1.0 percent. The penicillin used conforms to the requirements of § 146.24 (a), except the limitation of penicillin K content and except subparagraphs (1), (2), and (4) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each diluent conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Unless the penicillin for surface application is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, qual-

ity, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each immediate container (except when its content is two or more foil or film enclosures) and each foil or film enclosure shall contain not less than 10,000 units or more than 50,000 units and shall be so sealed that the contents cannot be used without destroying such seal.

(c) *Labeling.* Each package of penicillin for surface application shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container or in each foil or film enclosure therein, and the number of such foil or film enclosures;

(iii) The statement "Expiration date ----," the blank being filled in with the date which is 12 months after the month during which the batch was certified; and

(iv) In case the drug is not sterile, the statement "Not sterile—not for injection—not to be used in deep wounds or body cavities."

(2) On the outside wrapper or container;

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)";

(ii) If two or more such immediate containers or foil or film enclosures are in such packages, the number of such containers or foil or film enclosures therein and the number of units in each;

(iii) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----," the blank to be filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be;

(iv) The conditions under which solutions of penicillin for surface application should be stored, including a reference to their instability when stored under other conditions, and the statement "The solution may be kept in refrigerator for one week without significant loss of potency"; and

(v) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of penicillin for surface application; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such penicillin for surface application including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin for surface application shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container or foil or film enclosure, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the sodium chloride, milk sugar, sodium citrate, and dextrose used in making such batch conform to the standards prescribed therefor by the U. S. P.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per immediate container or foil or film enclosure, moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container or, if the drug is packed in foil or film enclosures, one such enclosure for each 5,000 such containers or enclosures in the batch, but in no case less than 20 such containers or enclosures or more than 100, collected by taking single containers or enclosures at such intervals throughout the entire time of packaging the batch, that the quantities packed during the intervals are approximately equal.

(ii) The penicillin used in making the batch; five packages containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin for surface application under the regulations in this part shall be:

(1) $1.00 for each immediate container or foil or film enclosure, whichever is the greatest number, in the samples submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such containers or enclosures, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.34 *Tablets aluminum penicillin*—(a) *Standards of identity, strength, quality, and purity.* Tablets aluminum penicillin are tablets composed of aluminum penicillin, sodium benzoate, with or without one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 50,000 units, and if it is less than 100,000 units it is "unscored". Each tablet contains 0.3 gram of sodium benzoate. Its moisture content is not more than 2 percent. The aluminum penicillin used conforms to the requirements of § 146.42 (a) for aluminum penicillin except subparagraphs (2) and (3) thereof. Each other substance used in the preparation of aluminum penicillin tablets, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet aluminum penicillin is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The number of tablets in the immediate container is such that the total number of units therein is not less than 300,000.

(c) *Labeling.* Each package of tablets aluminum penicillin shall bear, on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The quantity of sodium benzoate in each tablet;

(iv) The statement "Expiration date ----," the blank being filled in with the date which is 12 months after

the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(ii) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be.

(iii) Unless the drug is intended solely for verterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such tablets; or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of tablets aluminum penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each tablet; the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet, average moisture.

(ii) The aluminum penicillin used in making the batch; potency, moisture, pH, toxicity, and penicillin K content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The aluminum penicillin used in making the batch; 6 packages, each containing approximately equal portions of not less than 300 milligrams each, packaged in accordance with the requirements of § 146.42 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately five grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of tablets aluminum penicillin under this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.35 *Penicillin sulfonamide powder (calcium penicillin sulfonamide powder, crystalline penicillin sulfonamide powder)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin sulfonamide powder is composed of calcium penicillin or crystalline penicillin and one or both of the sulfonamides, sulfanilamide and sulfathiazole. It is sterile. Its moisture content is not more than 1.0 percent. The quantity of each sulfonamide used is not more than 0.05 gm. for each 100 units of penicillin used. The penicillin used conforms to the requirements of § 146.24 (a) except limitation on penicillin K content and except subparagraphs (1) and (4) of § 146.24 (a), but its potency is not less than 300 units per milligram. Each sulfonamide used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases, the immediate container of penicillin sulfonamide powder shall be a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, shall be sterile at the time of filling and closing, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. If the penicillin sulfonamide powder is packaged for "dusting" purposes each package shall contain not less than 5,000 units of penicillin. If the penicillin sulfonamide powder is packaged for dental use it shall be packaged in immediate containers of colorless, transparent glass meeting the test for glass containers of type I or type II prescribed by the U. S. P. The glass containers shall be open at both ends, one of which is constricted, both ends shall be capable of closure with rubber stoppers and each such container shall contain not less than 500 units of penicillin. Each package of penicillin sulfonamide powder for dental use shall contain a suitable device for insufflation purposes.

(c) *Labeling.* Each package of penicillin sulfonamide powder shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and immediate container:

(i) The batch mark;

(ii) The number of units in each immediate container;

(iii) The statement "Expiration date _____," the blank being filled in, if crystalline penicillin is used, with the date which is 18 months, or if crystalline penicillin is not used, with the date which is 9 months after the month during which the batch was certified;

(iv) If crystalline penicillin is not used, the statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(v) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be;

(vi) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such penicillin sulfonamide powder or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request;

(vii) On the label and the labeling, after the name penicillin sulfonamide powder wherever it appears, the words "with _____" in juxtaposition with such name, the blank being filled in with the name of the sulfonamide used.

(2) On the circular or other labeling within or attached to the package if it is intended solely for veterinary use, directions and precautions adequate for

the use of such penicillin sulfonamide powder, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin sulfonamide powder shall submit with his request a statement showing the batch mark; the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed; the number of units in each container of penicillin sulfonamide powder, the quantity of each ingredient used in making the batch, the date on which the latest assay of the penicillin sulfonamide powder comprising such batch was completed, and that such sulfonamide used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per container, average moisture, sterility.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, moisture, pH, crystallinity and heat stability if it is crystalline penicillin and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container of penicillin sulfonamide powder for each 5,000 containers in the batch, but in no case less than 20 such containers or more than 100, unless each such container is packaged to contain more than one gram in which case the sample shall consist of one gram for each 5,000 immediate containers in the batch, but in no case less than 20 grams or more than 100 grams. Such samples shall be collected by taking single immediate containers or one-gram portions at such intervals throughout the entire time the containers are being filled that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 mg., packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each sulfonamide used in making the batch; one package of each containing approximately five grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin sulfonamide powder under the regulations in this part shall be:

(1) $1.00 for each immediate container of penicillin sulfonamide powder in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such penicillin sulfonamide powder and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.36 *Penicillin vaginal suppositories—(a) Standards of identity, strength, quality, and purity.* Penicillin vaginal suppositories are suppositories composed of sodium penicillin, calcium penicillin, potassium penicillin, or procaine penicillin in a base of spermaceti and cocoa butter. The potency of each suppository is not less than 100,000 units; its moisture content is not more than 1.0%. The sodium penicillin, calcium penicillin, and potassium penicillin used conform to the requirements of § 146.24 (a), except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146.44 (a), except subparagraphs (2) and (3) of that paragraph. The spermaceti and cocoa butter used conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases, the immediate container of penicillin vaginal suppositories shall be a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin vaginal suppositories shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each suppository of the batch; and

(iii) The statement, "Expiration date ----------," the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(ii) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----------," the blank being filled in with the word "physician" or "veterinarian" or both as the case may be; and

(iii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such suppositories; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such suppositories, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin vaginal suppositories shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each suppository, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the spermaceti and cocoa butter used in making such batch conform to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per suppository, and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline sodium, potassium, or procaine penicillin G), crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one suppository for each 5,000 suppositories in the batch, but

in no case less than 20 suppositories or more than 100 suppositories, collected by taking single suppositories at such intervals throughout the entire time the suppositories are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch: 6 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 mg., if it is not procaine penicillin, and not less than 300 mg., if it is procaine penicillin, packaged in accordance with the requirements of § 146.24 (b) or § 146.44 (b).

(iii) In case of an initial request for certification, the spermaceti and cocoa butter used in making the batch: one package of each containing respectively approximately 10 grams and 100 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin vaginal suppositories under the regulations in this part shall be:

(1) $1.00 for each suppository in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such suppositories and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.37 *Buffered crystalline penicillin.* Buffered crystalline penicillin conforms to all requirements prescribed by § 146.24 for crystalline penicillin, and is subject to all procedures prescribed by § 146.24 for crystalline penicillin, except that:

(a) It contains the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids; such sodium citrate conforms to the standards prescribed therefor by the U. S. P.;

(b) If it is crystalline penicillin G, the penicillin G content is corrected for the sodium citrate content;

(c) The circular or other labeling within or attached to the package, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed for crystalline penicillin by § 146.24 (c) (3) (iii), the statement "Sterile solution may be kept in refrigerator for one week without significant loss of potency";

(d) A person who requests certification of a batch shall submit with his request a statement showing the quantity of sodium citrate used in making the batch, that such sodium citrate conforms to the requirements prescribed therefor by this section, and in case of an initial request for certification he shall submit an accurately representative sample of such sodium citrate consisting of approximately 5 grams; and

(e) The fee for the services rendered with respect to the sample of sodium citrate submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146.38 *Capsules buffered penicillin with pectin hydrolysate (capsules buffered potassium penicillin with pectin hydrolysate) — (a) Standards of identity, strength, quality and purity.* Capsules buffered penicillin with pectin hydrolysate are capsules composed of potassium penicillin with pectin hydrolysate and sodium citrate enclosed in a hard gelatin capsule. The potassium penicillin with pectin hydrolysate is prepared by lyophilizing a solution containing one part potassium penicillin and three parts of pectin hydrolysate by weight. The potency of each capsule is not less than 50,000 units. Its moisture content is not more than 4.0 percent. The penicillin used conforms to the requirements prescribed by § 146.24 (a) for potassium penicillin except subparagraphs (2) and (4) of § 146.24 (a). The pectin hydrolysate is obtained by mild hydrolysis of pectin with sodium hydroxide and hydrochloric acid. It is a free flowing and opalescent solution light tan to beige in color and is precipitated by the lower alcohols and ketones. Its pH is 6.0 to 7.0. It is substantially free of any turbidity or undissolved material. The pectin used conforms to the standards prescribed by the N. F. The sodium citrate and the sodium hydroxide and hydrochloric acid used in the preparation of the pectin hydrolysate conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Unless each capsule of buffered penicillin with pectin hydrolysate is enclosed in foil or plastic film and such enclosure complies with the definition of a tight container as prescribed by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the capsules by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The number of capsules in the immediate container is such that the total number of units therein is not less than 300,000.

(c) *Labeling.* Each package of capsules buffered penicillin with pectin hydrolysate shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each capsule of the batch;

(iii) The quantity of the sodium citrate in each capsule of the batch; and

(iv) The statement "Expiration date ---------," the blank being filled in with the date which is twelve months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ---------," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words, as the case may be.

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such capsules, or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such capsules, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of capsules buffered penicillin with pectin hydrolysate shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, and heat stability, and if it is crystalline penicillin G, penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities capsuled during the intervals are approximately equal.

(ii) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, one package of approximately 250 cc. of the pectin hydrolysate and one package of approximately five grams of the sodium citrate used in making the batch, one package of approximately 50 cc. of the hydrochloric acid and one package of approximately five grams of the sodium hydroxide used in preparing the pectin hydrolysate.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or such sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of capsules buffered penicillin with pectin hydrolysate under the regulations in this part shall be:

(1) $1.50 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.40 *Penicillin bougies (sodium penicillin bougies, calcium penicillin bougies, potassium penicillin bougies, procaine penicillin bougies, penicillin bougies sodium salt, penicillin bougies calcium salt, penicillin bougies potassium salt, penicillin bougies procaine salt)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin bougies are bougies composed of sodium penicillin, calcium penicillin, potassium penicillin, or procaine penicillin in an excipient of polyethylene glycol or of one or more other suitable and harmless diluents, binders, and lubricants. The potency of each bougie is not less than 25,000 units. Its moisture content is not more than 1.0 percent. The sodium penicillin, calcium penicillin, or potassium penicillin used conforms to the requirements of § 146.24 (a), except the limitation on penicillin K content and except subparagraphs (1), (2), and (4) of § 146.24 (a), but its potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146.44 (a), except the limitation on penicillin K content and except subparagraphs (2) and (3) of § 146.44 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin bougie is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the bougies by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin bougies shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each bougie of the batch;

(iii) The statement "Expiration date ----------," the blank being filled in, if crystalline penicillin or procaine penicillin is used without the excipient polyethylene glycol, with the date which is 18 months; or if the excipient polyethylene glycol is used, or if crystalline penicillin or procaine penicillin is not used, with the date which is 12 months after the month during which the batch was certified;

(iv) If the excipient is polyethylene glycol, the statement "Store in refrigerator not above 15° C. (59° F.)"; and

(v) The statement "For veterinary use only."

(2) On the circular or other labeling within or attached to the package, directions and precautions adequate for the use of such bougies, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin bougies shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each bougie, the quantity of each ingredient used in making the batch, and the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per bougie and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, and heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is crystalline procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one bougie for each 5,000 bougies in the batch, but in no case less than 20 bougies or more than 100 bougies, collected by taking single bougies at such intervals throughout the entire time the bougies are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 mg. if it is not procaine penicillin and not less than 300 mg. if it is procaine penicillin, packaged in accordance with the requirements of § 146.24 (b) or § 146.44 (b).

(iii) In case of an initial request for certification, each polyethylene glycol and each other ingredient used in making the batch; one package of each containing approximately 25 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin bougies under the regulations in this part shall be:

(1) $1.00 for each bougie in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such bougies and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a

certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.41 *Crystalline penicillin and epinephrine in oil*—(a) *Standards of identity, strength, quality, and purity.* Crystalline penicillin and epinephrine in oil is a suspension of crystalline penicillin and epinephrine in a menstruum of refined peanut oil or sesame oil. Each milliliter has a potency of 300,000 units and contains 0.3 milligram of epinephrine. Its moisture content is not more than 0.2 percent. It is sterile. The penicillin used conforms to the requirements of § 146.24 (a) for crystalline penicillin. The epinephrine, peanut oil and sesame oil used conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* The immediate container of crystalline penicillin and epinephrine in oil shall be of colorless transparent glass so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of crystalline penicillin and epinephrine in oil in each such container shall be not less than one milliliter and not more than 20 milliliters unless it is packaged for repacking. Unless it is packaged for repacking each container shall be filled with a volume of crystalline penicillin and epinephrine in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(c) *Labeling.* Each package of crystalline penicillin and epinephrine in oil shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The quantity of epinephrine per milliliter of the batch;

(iv) The statement "Expiration date ------," the blank being filled in with the date which is 18 months after the month during which the batch was certified;

(v) The statement "For intramuscular use only" and "Shake well"; and

(vi) The name of the oil used in making the batch.

(2) On the circular or other labeling within or attached to the package, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including site of injection;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including sensitization.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the epinephrine, peanut oil or sesame oil used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture and epinephrine content;

(ii) The penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, heat stability and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 500 packages in the batch, but in no case less than 5 packages or more than 15 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, the epinephrine and the peanut oil or sesame oil used in making the batch; one package of each containing approximately 2 grams and 250 grams respectively.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of crystalline penicillin and epinephrine in oil under the regulations in this part shall be:

(1) $4.00 for each immediate container submitted in accordance with paragraph (d) (3) (i), $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examinations of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fees prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.42 *Aluminum penicillin (aluminum penicillin salt)*—(a) *Standards of identity, strength, quality, and purity.* Aluminum penicillin is the insoluble aluminum salt of a kind of penicillin or a mixture of two or more such salts, but the quantity of any salt of penicillin K therein is not more than 30 percent. Each such drug is so purified and dried that:

(1) Its potency is not less than 500 units per milligram;

(2) It is sterile;

(3) It is nonpyrogenic;

(4) It is nontoxic;

(5) Its moisture content is not more than 3 percent; and

(6) Its pH in saturated aqueous solution is not less than 3.5 and not more than 4.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of aluminum penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;

(2) The weight of the drug and the number of units in the immediate container;

(3) The statement "Expiration date ---------", the blank being filled in with the date which is 12 months after the month during which the batch was certified;

(4) The statement "Store in refrigerator not above 15° C. (59° F.)", or "Store below 15° C. (59° F.)"; and

(5) The statement "For manufacturing use only."

(d) *Request for certification, check tests, and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aluminum penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was

previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed with results of the tests and assays made by him on the batch for potency, sterility, pyrogens, toxicity, moisture, pH, and the penicillin K content.

(2) Such person shall submit with his request a sample containing six approximately equal portions of not less than 300 milligrams each taken from different parts of such batch; each portion shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which aluminum penicillin is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of each check test and assay as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraphs (d) (2) and (3) of this section; and

(2) If the Commissioner considers that investigations, other than the examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.43 *Aluminum penicillin in oil*—(a) *Standards of identity, strength, quality, and purity.* Aluminum penicillin in oil is a suspension of aluminum penicillin in a menstruum of refined peanut oil or sesame oil. Its potency is 300,000 units per milliliter. Its moisture content is not more than 1.5 percent. It is sterile. The aluminum penicillin used conforms to the requirements of § 146.42 (a).

The peanut oil or sesame oil used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* The immediate container of aluminum penicillin in oil shall be of colorless, transparent glass, so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of aluminum penicillin in oil in each such container shall be not less than 1 milliliter and not more than 20 milliliters, unless it is packaged for repacking. Unless it is packaged for repacking, each container shall be filled with a volume of aluminum penicillin in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses.

(c) *Labeling.* Each package of aluminum penicillin in oil shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside label or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 12 months after the month during which the batch was certified;

(iv) The statements "For intramuscular use only" and "Shake well";

(v) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)"; and

(vi) The name of the oil used in making the batch.

(2) On the circular or other labeling within or attached to the package, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including site of injection;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including sensitization.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aluminum penicillin in oil shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the aluminum penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the peanut oil or sesame oil used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture;

(ii) The aluminum penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 500 packages in the batch, but in no case less than 3 packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal;

(ii) The aluminum penicillin used in making the batch; 6 packages containing approximately equal portions of not less than 300 milligrams, each packaged in accordance with the requirements of § 146.42 (b);

(iii) In case of an initial request for certification, the peanut oil or sesame oil used in making the batch; one package of each containing approximately 250 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph and no sample referred to in subparagraph (3) (ii) of this paragraph are required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of aluminum penicillin in oil under the regulations in this part shall be:

(1) $8.00 for each package submitted in accordance with paragraph (d) (3) (i), $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than the examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.44 *Procaine penicillin (penicillin procaine salt), procaine penicillin G (penicillin G procaine salt)*—(a) *Standards of identity, strength, quality, and purity.* Procaine penicillin is the crystalline procaine salt of a kind of penicillin, or a mixture of two or more such salts prepared from procaine hydrochloride U. S. P. and penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; procaine penicillin G is procaine penicillin which contains not less than 85 percent by weight of the procaine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 900 units per milligram;

(2) It is sterile;

(3) It is nonpyrogenic;

(4) It is nontoxic;

(5) Its moisture content is not more than 4.2 percent; and

(6) Its pH in saturated aqueous solution is not less than 5 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of procaine penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;

(2) The weight of the drug and the number of units in the immediate containers;

(3) The statement "Expiration date ----------," the blank being filled in with the date which is 24 months after the month during which the batch was certified; and

(4) The statement "For manufacturing use only."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of procaine penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(2) Such person shall submit with his request a sample containing 10 approximately equal portions of at least 300 milligrams each taken from different parts of such batch. Each such portion shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which procaine penicillin is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to each manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) and (3) of this section; and

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.45 *Procaine penicillin in oil*—(a) *Standards of identity, strength, quality, and purity.* Procaine penicillin in oil is a suspension of procaine penicillin in refined peanut oil or sesame oil, with or without the addition of one or more suitable and harmless dispersing agents and with or without the addition of a hardening agent. Its potency is 300,000 units per milliliter, except if it is packaged and labeled solely for veterinary use, its potency is not less than 10,000 units per milliliter. Its moisture content is not more than 1.4 percent. It is sterile, unless it is packaged and labeled solely for udder instillations of cattle. The procaine penicillin used conforms to the requirements of § 146.44 (a), except if the batch of procaine penicillin in oil is packaged and labeled solely for udder instillations of cattle, the penicillin used is exempt from the requirements of subparagraphs (2) and (3) of that section. The sesame oil and peanut oil used conform to the standards prescribed therefor by the U. S. P. The hardening agent is a refined hydrogenated and deodorized peanut oil free from rancidity; it has an iodine value of not more than 10; its free fatty acid content as oleic acid is not more than $\frac{1}{10}$ of 1 percent, and its melting point is 64° C., ±2° C.

(b) *Packaging.* The immediate container of procaine penicillin in oil shall be of colorless transparent glass so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that its contents cannot be used without destroying such seal, except if it is labeled solely for udder instillations of cattle, it may be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P. The immediate container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limitation therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good marketing, storage, and distribution practice shall be disregarded. The quantity of procaine penicillin in oil in each glass container shall be not less than 1 ml. and not more than 20 ml., unless it is packaged for repacking or is packaged and labeled solely for veterinary use. Unless it is packaged for repacking, each glass container shall be filled with a volume of procaine penicillin in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in single or multiple doses.

(c) *Labeling.* Each package of procaine penicillin in oil shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 24 months after the month during which the batch was certified;

(iv) Unless it is packaged and labeled solely for udder instillations of cattle, the statement "For intramuscular use only" and, if it does not contain a hardening agent, "Shake well"; and

(v) The name of each oil used in making the batch, and, if aluminum monostearate is used as the dispersing agent, the quantity used.

(2) On the circular or other labeling within or attached to the package, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including site of injection;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including sensitization.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of procaine penicillin in oil shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the procaine penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each ingredient used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: potency, sterility (unless it is intended solely for udder instillations of cattle), and moisture.

(ii) The procaine penicillin used in making the batch: potency, toxicity, moisture, pH, crystallinity, penicillin K content (unless it is crystalline penicillin G), procaine penicillin G content if it is procaine penicillin G, and, unless the batch of procaine penicillin in oil is intended solely for udder instillations of cattle, sterility and pyrogens.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection

with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 500 packages in the batch, but in no case less than three packages nor more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; 10 packages containing approximately 300 milligrams each, packaged in accordance with the requirements of § 146.44 (b).

(iii) In case of an initial request for certification, the peanut oil or sesame oil and each dispersing and hardening agent used in making the batch; one package of each containing, respectively, approximately 250 grams and 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fees for the services rendered with respect to each batch of procaine penicillin in oil under the regulations in this part shall be:

(1) $4.00 for each package submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.46 *Crystalline penicillin for inhalation therapy—(a) Standards of identity, strength, quality, and purity.* Crystalline penicillin for inhalation therapy is crystalline sodium penicillin, potassium penicillin, or procaine penicillin, with or without one or more suitable and harmless diluents. Its moisture content is not more than 1.5% if it is crystalline sodium or potassium penicillin, and not more than 4.2 percent if it is procaine penicillin. The crystalline penicillin used conforms to the requirements of § 146.24 (a) except subparagraphs (2) and (4) of that paragraph. The procaine penicillin used conforms to the requirements of § 146.44 (a), except subparagraphs (2) and (3) of that paragraph. Each diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container of crystalline penicillin for inhalation therapy shall be a tight container as defined by the U. S. P.; its closure shall be one through which a hypodermic needle cannot be introduced; and the container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 50,000 units and each may be packaged in combination with a container of the solvent, distilled water U. S. P., physiological salt solution U. S. P., physiological salt solution with the preservative chlorobutanol, or a solution of propylene glycol in distilled water.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date _____," the blank being filled in, if crystalline sodium penicillin or potassium penicillin is used, without a diluent, with the date which is 36 months; or if crystalline sodium penicillin or potassium penicillin is used, with a diluent, or if procaine penicillin is used, with the date which is 18 months after the month during which the batch was certified; and

(iv) If it is packaged in combination with a container of a solvent, the statement "Warning—Not for Injection."

(2) On the outside wrapper or container.

(i) The statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or both, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such crystalline penicillin for inhalation therapy; or a reference to a brochure, or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of crystalline penicillin for inhalation therapy shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container, the quantity of each diluent used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each diluent used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 20 immediate containers or more than 100 immediate containers, collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 mg. if it is not procaine penicillin, and not less than 300 mg. if it is procaine penicillin, packaged in accordance with the requirements of § 146.24 (b) or § 146.44 (b).

(iii) In case of an initial request for certification, each diluent used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i); $4.00 for each package in the samples submitted in acordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.47 *Procaine penicillin for aqueous injection—(a) Standards of identity, strength, quality, and purity.* Procaine penicillin for aqueous injection is a dry mixture of procaine penicillin and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless buffer

substances, or it is an aqueous suspension of procaine penicillin and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives, except that preservatives are not required if the immediate container is packaged to contain a single dose and is conspicuously so labeled. It is so purified that:

(1) If it is an aqueous suspension of the drug, its potency is 300,000 units or 600,000 units per milliliter, unless the immediate container is packaged to contain a single dose (and is conspicuously so labeled) of 300,000 units in a volume of less than 1 ml. or 600,000 units in a volume of less than 2 ml.;

(2) It is sterile;

(3) If it is the dry mixture of the drug, its moisture content is not more than 4.2%;

(4) It is nonpyrogenic;

(5) It is nontoxic; and

(6) Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

The procaine penicillin used conforms to the requirements of § 146.44 (a). Each other substance, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless, transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. If it is the dry mixture of the drug, each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,200,000 units, 1,500,000 units, or 3,000,000 units, and each may be packaged in combination with a container of a suitable aqueous diluent. If it is the aqueous suspension of the drug, each such container shall contain not less than 1 ml. (unless it is packaged to contain a single dose) and not more than 10 ml., and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date ——————," the blank being filled in, if it is a dry mixture of the drug, with the date which is 18 months, or if it is the aqueous suspension of the drug, with the date which is 12 months after the month during which the batch was certified;

(iv) The statement "For intramuscular use only"; and

(v) If the drug contains preservatives, the name and quantity of each preservative used.

(2) On the outside wrapper or container, if it is the aqueous suspension of the drug, the statement "Store below 25° C. (77° F.)."

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparing the drug for injection;

(iii) If it is the dry mixture of the drug, the conditions under which suspensions made from such drug should be stored, and the statement "Sterile suspension may be kept at room temperature for 1 week, or in refrigerator for 3 weeks, without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of procaine penicillin for aqueous injection shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the procaine penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, pyrogens, toxicity, pH, and

(ii) The procaine penicillin used in making the batch; potency, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than 10 and not more than 17 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal;

(ii) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 500 mg. each, packaged in accordance with the requirements of § 146.44 (b);

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 gm;

(iv) In case of an initial request for the certification of a batch of procaine penicillin for aqueous injection which is to be packaged in combination with an aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of such diluent, five packages of the diluent included in the combination.

(4) If such batch is packed for repacking, such person shall submit with his request a sample containing 10 approximately equal portions of at least 300 milligrams each taken from different parts of such batch; each such portion shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) Four dollars for each immediate container in the sample submitted in accordance with paragraph (d) (3) and (4) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.48 *Ephedrine penicillin (penicillin ephedrine salt), ephedrine penicillin G (penicillin G ephedrine salt)*—(a) *Standards of identity, strength, quality, and purity.* Ephedrine penicillin is the crystalline ephedrine salt of a kind of penicillin, or a mixture of two or more such salts prepared from ephedrine

U. S. P. and penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; ephedrine penicillin G is ephedrine penicillin which contains not less than 85 percent by weight of the ephedrine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 1,000 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 1.5 percent;

(6) Its pH in aqueous solution of 5,000 to 10,000 units per milliliter is not less than 5 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of ephedrine penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;

(2) The weight of the drug and the number of units in the immediate container;

(3) The statement "Expiration date ----------", the blank being filled in with the date which is 12 months after the month during which the batch was certified; and

(4) The statement "For manufacturing use only."

(d) *Requests for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of ephedrine penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, penicillin K content (unless it is ephedrine penicillin G), and the penicillin G content if it is ephedrine penicillin G.

(2) Such person shall submit with his request a sample containing 10 approximately equal portions of at least 300 milligrams each taken from different parts of such batch. Each such portion shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(3) In connection with the contemplated requests for certification of batches of another drug in the manufacture of which ephedrine penicillin is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to each manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) and (3) of this section; and

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed under subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.49 *Ephedrine penicillin tablets—*(a) *Standards of identity, strength, quality, and purity.* Ephedrine penicillin tablets are tablets composed of ephedrine penicillin and one or more buffer substances, with or without one or more suitable and harmless diluents, binders, and lubricants. The potency of each tablet is not less than 30,000 units. Its moisture content is not more than 1.5 percent. When a tablet is dissolved as directed the potency of such solution is not less than 4,000 units per milliliter after it has been kept for one day at a temperature of 15° C. (59° F). Such solution is isotonic, and has a pH of 6.0, ±0.2. The ephedrine penicillin used conforms to the requirements of § 146.48 (a) for ephedrine penicillin except subparagraphs (2) and (4) of § 146.48 (a). Each buffer substance and preservative used, if their names are recognized in the U. S. P. or N. F., conform to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of tablets ephedrine penicillin shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 24 months after the month during which the batch was certified;

(iv) A statement giving the method of dissolving the tablets, and a statement that distilled water U. S. P. should be used;

(v) The potency per milliliter after the tablet has been dissolved therein;

(vi) The statement "Warning—Not for injection or oral use"; and

(vii) The conditions under which the solution should be stored including a reference to its instability when stored under other conditions, and a statement "Prepare a fresh solution each 24 hours."

(2) On the outside wrapper or container, unless it is intended solely for veterinary use and is conspicuously so labeled:

(i) The statement "Caution: To be dispensed only by or on the prescription of a ----------," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of the tablets; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) If intended solely for veterinary use, directions and precautions adequate for the use of such tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying to the requirements of § 146.2, a person who requests certification of a batch of ephedrine penicillin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the ephedrine penicillin used in making such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising the batch was completed, and a statement that each ingredient used in making the batch con-

forms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The ephedrine penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is ephedrine penicillin G), crystallinity, and the penicillin G content if it is ephedrine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal;

(ii) The ephedrine penicillin used in making the batch; six packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146.48 (b); and

(iii) In case of an initial request for certification, each buffer substance, diluent, binder, and lubricant used in making the batch; one package of each, each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for services rendered with respect to each batch of ephedrine penicillin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.50 *Procaine penicillin and buffered crystalline penicillin for aqueous injection.* Procaine penicillin and buffered crystalline penicillin for aqueous injection conforms to all requirements prescribed by § 146.47 for the dry mixture of procaine penicillin for aqueous injection, and is subject to all procedures prescribed by § 146.47 for the dry mixture of procaine penicillin for aqueous injection, except that:

(a) Its potency is such that when the diluent is added as directed, each milliliter shall contain not less than 300,000 units of procaine penicillin and not less than 50,000 units of buffered crystalline penicillin. The buffered crystalline penicillin conforms to the requirements prescribed therefor by § 146.37.

(b) If it is packaged as a single dose and its immediate container has two compartments separated by a tight rubber seal, one compartment shall contain an aqueous suspension of procaine penicillin which conforms to all requirements and procedures prescribed by § 146.47 and one compartment shall contain the dry buffered crystalline penicillin.

(c) In lieu of the directions prescribed for procaine penicillin for aqueous injection by § 146.47 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin and the number of units of buffered crystalline penicillin in the immediate container; the circular or other labeling within or attached to the package, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed by § 146.47 (c) (3) (iii), the statement "Sterile suspension may be kept in refrigerator for one week without significant loss of potency," unless it is packaged to conform with paragraph (b) of this section.

(d) In addition to complying with the requirements of § 146.47 (d), a person who requests certification of a batch of procaine penicillin and buffered crystalline penicillin for aqueous injection shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the buffered crystalline penicillin used in making the batch for potency, crystallinity, heat stability, penicillin K content (unless it is buffered crystalline penicillin G) and the penicillin G content if it is buffered crystalline penicillin G, the number of units of procaine penicillin and the number of units of buffered crystalline penicillin in each immediate container of the batch. He shall also submit in connection with his request a sample consisting of three packages containing approximately equal portions of not less than 250 mg. each of the buffered crystalline penicillin used in making the batch. If such batch is packaged for repacking, such person shall submit with his request a sample containing 10 approximately equal portions of at least 400 mg. each packaged in accordance with the requirements prescribed by § 146.47 (b).

(e) The fee for the services rendered with respect to each immediate container in the sample of buffered crystalline penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146.51 *Buffered penicillin powder—* (a) *Standards of identity, strength, quality, and purity.* Buffered penicillin powder is a mixture of crystalline penicillin or procaine penicillin and suitable buffer substances, with or without two or more suitable sulfonamides, and with or without the addition of one or more suitable and harmless diluents, colorings, and flavorings. Its moisture content is not more than 1.0 percent, except if it contains procaine penicillin its moisture content is not more than 2.0 percent. The crystalline penicillin used conforms to the requirements of § 146.24 (a) for crystalline penicillin, except subparagraphs (2) and (4) of that paragraph. The procaine penicillin used conforms to the requirements of § 146.44 (a), except subparagraphs (2) and (3) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container of buffered penicillin powder shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each immediate container shall contain not less than 600,000 units and each may be packaged in combination with a container of a suitable and harmless aqueous vehicle, with or without two or more suitable sulfonamides.

(c) *Labeling.* Each package of buffered penicillin powder shall bear on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) If the batch contains sulfonamides, the name and quantity of each such sulfonamide used in making the batch;

(iv) If it is a packaged combination of one immediate container of buffered penicillin powder and one immediate container of a vehicle, a statement giving the method of dissolving the penicillin;

(v) The name of each buffer substance used in making the batch;

(vi) The statement "Expiration date ----------," the blank being filled in with the date which is 18 months after the month during which the batch was certified; and

(vii) The statement "Warning—Not for injection."

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words, as the case may be;

(ii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication

containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such buffered penicillin powder; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the label and labeling, if sulfonamides are present, after the name "Buffered penicillin powder," wherever it appears, the words "with sulfonamides," in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such buffered penicillin powder, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including those for any buffer substance present.

If two or more such immediate containers are in such package the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of buffered penicillin powder shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 20 immediate containers or more than 100 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 mg. if it is not procaine penicillin, and not less than 500 mg. if it is procaine penicillin, packaged in accordance with the requirements of § 146.24 (b) or § 146.44 (b).

(iii) In case of an initial request for certification, each buffer substance, diluent, coloring, or flavoring used in making the batch; one package of each containing approximately 5 gm.

(iv) In case of an initial request for the certification of a batch of buffered penicillin powder which is to be packaged in combination with an aqueous vehicle, or when any change is made in the composition of such aqueous vehicle, 5 packages of the vehicle included in the combination.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of buffered penicillin powder under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii), (iii), and (iv) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.52 *Procaine penicillin and crystalline penicilin in oil.* (a) Procaine penicillin and crystalline penicillin in oil conforms to all requirements prescribed by § 146.45 for procaine penicillin in oil, and is subject to all procedures prescribed by § 146.45 for procaine penicillin in oil, except that:

(1) It contains not less than 50,000 units of crystalline penicillin for each 300,000 units of procaine penicillin, except if it is packaged and labeled solely for veterinary use, it contains not less than 3,000 units of crystalline penicillin for each 10,000 units of procaine penicillin. The crystalline penicillin used conforms to the requirements prescribed therefor by § 146.24 (a), except if the batch of procaine penicillin and crystalline penicillin in oil is intended solely for udder instillations of cattle, the crystalline penicillin used is exempt from the requirements of subparagraphs (2) and (4) of that section.

(2) In lieu of the directions prescribed for procaine penicillin in oil by § 146.45 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin and the number of units of crystalline penicillin in each milliliter of the batch.

(3) In addition to complying with the requirements of § 146.45 (d), a person who requests certification of a batch of procaine penicillin and crystalline penicillin in oil shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the crystalline penicillin G used in making the batch for potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, heat stability, the penicillin G content if it is crystalline penicillin G, and, unless the batch of procaine penicillin and crystalline penicillin in oil is intended solely for udder instillations of cattle, sterility and pyrogens; the number of units of procaine penicillin and the number of units of crystalline penicillin in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of not less than four packages of the batch of procaine penicillin and crystalline penicillin in oil, and a sample consisting of 10 packages containing approximately equal portions of not less than 60 mg. each of the crystalline penicillin used in making such batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of crystalline penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146.53 *Penicillin for diagnostic use; streptomycin for diagnostic use; dihydrostreptomycin for diagnostic use; aureomycin for diagnostic use; chloramphenicol for diagnostic use; bacitracin for diagnostic use.* Tablets, discs, or other such forms of penicillin, streptomycin, dihydrostreptomycin, aureomycin, chloramphenicol, or bacitracin intended for use solely in laboratory procedures in connection with the diagnosis or treatment of disease, and conspicuously so labeled, shall be exempt from the requirements of section 502 (l) and 507 of the act, if the potency of each such tablet, disc, or other such form is not more than 50 units in the case of pencillin, or more than 20 units in the case of bacitracin, or more than 60 micrograms in the case of aureomycin or chloramphenicol, or more than 100 micrograms in the case of streptomycin or dihydrostreptomycin.

§ 146.54 *Penicillin-streptomycin ointment (penicillin-streptomycin mineral oil suspension), penicillin-dihydrostreptomycin ointment (penicillin-dihydrostreptomycin mineral oil suspension.)* (a) Penicillin-streptomycin ointment and penicillin-dihydrostreptomycin ointment conform to all requirements prescribed by § 146.26 for penicillin ointment, except paragraph (c) (2) (i) of that section, and are subject to all procedures prescribed by § 146.26 for penicillin ointment, except that:

(1) It contains not less than 2,000 units of penicillin per gram.

(2) It contains not less than 10 mg. of streptomycin or dihydrostreptomycin per gram, unless it is intended solely for veterinary use and is conspicuously so labeled. The streptomycin used conforms to the standards prescribed by § 146.101 (a), except subparagraphs (2), (4), and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by § 146.103, except the standards for sterility, pyrogens, and histamine.

(3) If it is intended solely for veterinary use and is conspicuously so labeled, it may contain one or more of the sulfonamides.

(b) In lieu of the directions prescribed for penicillin ointment by § 146.26 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin per gram and the number of milligrams of streptomycin or dihydrostreptomycin per gram, and if it contains one or more of the sulfonamides, the quantity of each.

(c) In addition to complying with the requirements of § 146.26 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate. He shall also submit in connection with his request a sample consisting of not less than six packages of such ointment and (unless it was previously submitted) a sample consisting of five packages containing approximately equal portions of not less than 0.5 gm. each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146.101 (b).

(d) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146.55 *Penicillin-streptomycin bougies, penicillin-dihydrostreptomycin bougies.* (a) Penicillin-streptomycin bougies and penicillin-dihydrostreptomycin bougies conform to all requirements prescribed by § 146.40 for penicillin bougies and are subject to all procedures prescribed by § 146.40 for penicillin bougies, except that:

(1) Each bougie contains not less than 25 mg. of streptomycin or dihydrostreptomycin.

(2) In lieu of the directions prescribed for penicillin bougies by § 146.40 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each bougie.

(3) In addition to complying with the requirements of § 146.40 (d), a person who requests certification of a batch of penicillin-streptomycin bougies or penicillin-dihydrostreptomycin bougies shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, and its streptomycin content if it is dihydrostreptomycin; the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each bougie of the batch. He shall also submit in connection with his request a sample consisting of not less than thirty bougies and (unless it was previously submitted) a sample consisting of five packages containing approximately equal portions of not less than 0.5 gm. each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146.101 (b).

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $4.00.

§ 146.56 *Penicillin-bacitracin ointment.* (a) Penicillin-bacitracin ointment conforms to all requirements prescribed by § 146.26 for penicillin ointment and is subject to all procedures prescribed by § 146.26 for penicillin ointment, except that:

(1) It contains not less than 2,000 units of penicillin per gram;

(2) It contains not less than 500 units of bacitracin per gram;

(3) In lieu of the directions prescribed for penicillin ointment by § 146.26 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin per gram and the number of units of bacitracin per gram;

(4) In addition to complying with the requirements of § 146.26 (d) a person who requests certification of a batch of penicillin-bacitracin ointment shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the bacitracin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than six packages of penicillin-bacitracin ointment and (unless it was previously submitted) a sample consisting of six packages containing approximately equal portions of not less than 0.5 gm. each of the bacitracin used in making the batch, packaged in accordance with the requirements of § 146.401 (b).

(b) The fee for the services rendered with respect to each immediate container in the sample of bacitracin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146.57 *Procaine penicillin and streptomycin in oil, procaine penicillin and dihydrostreptomycin in oil.* (a) Procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil conform to all requirements prescribed by § 146.45 for procaine penicillin in oil for udder instillations of cattle and are subject to all procedures prescribed by § 146.45 for procaine penicillin in oil for udder instillations of cattle, except that:

(1) It contains not less than 6.7 mg. of streptomycin or dihydrostreptomycin per milliliter. The streptomycin used conforms to the standards prescribed by § 146.101 (a), except subparagraphs (2), (4), and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by § 146.103, except the standards for sterility, pyrogens, and histamine.

(2) In lieu of the directions prescribed for procaine penicillin in oil by § 146.45 (c) (1) (ii) and (iv) each package shall bear on the outside wrapper or container and on the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch and the statements "For udder instillations of cattle only," and if it is a multiple-dose container, "Shake well."

(3) In addition to complying with the requirements of § 146.45 (d), a person who requests certification of a batch of procaine penicillin and streptomycin in oil or procaine penicillin and dihydrostreptomycin in oil shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin; the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of not less than four immediate containers of the batch and (unless it was previously submitted) a sample consisting of five packages containing approximately equal portions of not less than 0.5 gm. each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146.101 (b).

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $4.00.

§ 146.58 *Penicillin and streptomycin, penicillin and dihydrostreptomycin*—(a) *Standards of identity, strength, quality, and purity.* Penicillin and streptomycin is procaine penicillin or crystalline sodium penicillin or potassium penicillin or a mixture of procaine penicillin and crystalline sodium penicillin or potassium penicillin and streptomycin sulfate. Penicillin and dihydrostreptomycin is procaine penicillin or crystalline sodium penicillin or potassium penicillin or a mixture of procaine penicillin and crystalline sodium penicillin or potassium penicillin and dihydrostreptomycin sulfate. Each such drug may contain suitable and harmless buffer substances,

suspending or dispersing agents. It is so purified and dried that:

(1) It is sterile;

(2) It is nontoxic;

(3) It is nonpyrogenic;

(4) Its moisture content is not more than 3.5 percent; and

(5) When prepared for injection as directed in its labeling its pH is not less than 5.0 and not more than 7.5.

The procaine penicillin used conforms to the requirements prescribed by § 146.44 (a). The crystalline penicillin used conforms to the requirements prescribed for crystalline penicillin by § 146.24 (a). The streptomycin sulfate used conforms to the requirements prescribed by § 146.101 (a). The dihydrostreptomycin sulfate used conforms to the requirements prescribed by § 146.106 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases, the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless, transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,500,000 units or 3,000,000 units of procaine penicillin or crystalline sodium penicillin or potassium penicillin and not less than 0.5 gm. of streptomycin or dihydrostreptomycin for each 300,000 units of penicillin, except if it is a mixture of two salts of penicillin it shall contain not less than 100,000 units of crystalline sodium penicillin or potassium penicillin for each 300,000 units of procaine penicillin. Each such container may be packaged in combination with a container of a solvent, water for injection U. S. P., dextrose injection U. S. P., or physiological salt solution U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container:

(i) The batch mark;

(ii) The number of units of each salt of penicillin in the immediate container;

(iii) The number of grams of streptomycin or dihydrostreptomycin in the immediate container;

(iv) The statement "Expiration date ____," the blank being filled in with the date which is 18 months after the month in which batch was certified;

(v) The statement "For intramuscular use only"; and

(vi) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warning as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration including method of preparing the drug for injection;

(iii) The conditions under which suspensions made from such drug should be stored, and the statement "Sterile suspension may be kept in refrigerator for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin and streptomycin or penicillin and dihydrostreptomycin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of units of each salt of penicillin, and the number of grams of streptomycin or dihydrostreptomycin in each package, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the penicillin and streptomycin or dihydrostreptomycin used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: potency, sterility, toxicity, pyrogens, moisture, pH.

(ii) The procaine penicillin used in making the batch; potency, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(iii) The crystalline sodium or potassium penicillin used in making the batch; potency, crystallinity, heat stability, penicillin K content (unless it is crystalline penicillin G), and the penicillin G content if it is crystalline penicillin G.

(iv) The streptomycin or dihydrostreptomycin used in making the batch; potency, histamine content, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request in the quantities hereinafter indicated accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 12 or more than 19 immediate containers collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gm. each packaged in accordance with the requirements of § 146.44 (b).

(iii) The crystalline penicillin used in making the batch, 3 packages containing approximately equal portions of not less than 250 mg. each packaged in accordance with the requirements of § 146.24 (b).

(iv) The streptomycin or dihydrostreptomycin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gm. each packaged in accordance with the requirement of § 146.101 (b).

(v) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 gm.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample containing twelve approximately equal portions of at least 2 gm. each taken from different parts of such batch, each such portion shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), and (iv) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) and (4) of this section; and

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee

is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.59 *Penicillin tooth powder (tooth powder with penicillin)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin tooth powder is a mixture of crystalline penicillin and one or more suitable cleansing and polishing substances, with or without suitable and harmless diluents, colorings, and flavorings. Its potency is 500 units per gram. Its moisture content is not more than 2.0%. The crystalline penicillin used conforms to the requirements of § 146.24 (a) for crystalline penicillin, except the limitation on penicillin K content and except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not more than 3 ounces.

(c) *Labeling.* Each package of penicillin tooth powder shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units per gram of the batch; and

(iii) The statement "Expiration date _____," the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or both, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such penicillin tooth powder; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent to physicians and dentists on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of penicillin tooth powder shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of.

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, heat stability, and the penicillin G content if it is crystalline sodium or potassium penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 mg., packaged in accordance with the requirements of § 146.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin tooth powder under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.101 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride (streptomycin calcium chloride complex)*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate is the sulfate salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin hydrochloride is the hydrochloride salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin phosphate is the phosphate salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin trihydrochloride calcium chloride is the double salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug is so purified and dried that:

(1) Its potency is not less than 300 micrograms per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) It contains no histamine or histamine-like substances;

(6) Its moisture content is not more than 5.0 percent;

(7) Its pH in aqueous solution of 0.2 gram per millimeter is not less than 4.5 and not more than 7.0.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless transparent glass closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 0.5 gram, 1.0 gram, 2.0 grams, 3.0 grams, 4.0 grams, 5.0 grams, or 10.0 grams, and each may be packaged in combination with a container of the solvent ,water for injection U. S. P., dextrose injection 5 percent U. S. P., or physiological salt solution U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of grams in the immediate container;

(iii) The statement "Expiration date _____", the blank being filled in with the date which is 24 months after the month during which the batch was certified; and

(iv) The statement "For Manufacturing Use", "For Repacking", or "For Manufacturing Use or Repacking" when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparation and

strength of solutions for different routes of injection and local application;

(iii) The conditions under which such solutions should be stored including the statement "Sterile solution may be stored at room temperature for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification, check tests, and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of grams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, moisture, and pH. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than 5 or more than 12 immediate containers.

Such sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing five approximately equal portions of at least 0.5 gram each taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the sample submitted in accordance with paragraphs (d) (2), (3), and (4) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.102 *Streptomycin ointment, dihydrostreptomycin ointment.*

(a) *Standards of identity, strength, quality, and purity.* Streptomycin ointment and dihydrostreptomycin ointment is streptomycin or dihydrostreptomycin in a suitable and harmless ointment base, with or without suitable and harmless dispersing and suspending agents. Its potency is not less than 5,000 micrograms per gram of ointment. The streptomycin used conforms to the requirements of § 146.101 (a), except subparagraphs (2), (4), (5), and (6) of that paragraph. The dihydrostreptomycin used conforms to the requirements of § 146.103, except the standards for sterility, pyrogens, histamine, and moisture. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Streptomycin ointment and dihydrostreptomycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P., and each such tube shall not be larger than the 2-ounce size, except if it is labeled solely for hospital use it may be packaged in immediate containers of glass which meet the test for tight containers as defined by the U. S. P. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of streptomycin ointment shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of micrograms per gram of the batch; and

(iii) The statement "Expiration date _____," the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such ointment, or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such ointment, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of streptomycin ointment or dihydrostreptomycin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers unless each such container is packaged for hospital use and contains more than 2 ounces, in which case the sample shall consist of ap-

proximately 1 ounce of ointment for each 5,000 immediate containers in the batch, but in no case less than five 1-ounce portions or more than twelve 1-ounce portions. Such sample shall be collected by taking single immediate containers or 1-ounce portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages containing approximately equal portions of not less than 0.5 gm. each, packaged in accordance with the requirements of § 146.101 (b).

(iii) In case of an initial request for certification, the ingredients used in making the ointment base of the batch; one package of each containing approximately 200 gm., except for the suspending and dispersing agents used, in which case the sample shall consist of approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of streptomycin ointment or dihydrostreptomycin ointment under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.103 *Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride.* (a) Dihydrostreptomycin sulfate is the hydrogenated sulfate salt of a kind of streptomycin or a mixture of two or more such salts; crystalline dihydrostreptomycin sulfate is the hydrogenated crystalline sulfate salt of a kind of streptomycin or a mixture of two or more such salts; dihydrostreptomycin hydrochloride is the hydrogenated hydrochloride salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug conforms to all requirements prescribed by § 146.101 for streptomycin sulfate and streptomycin hydrochloride, and is subject to all procedures prescribed by § 146.101 for streptomycin sulfate and streptomycin hydrochloride, except that:

(1) Its potency is not less than 600 micrograms per milligram, except that if it is crystalline dihydrostreptomycin sulfate its potency is not less than 725 micrograms per milligram.

(2) Its content of streptomycin sulfate or streptomycin hydrochloride is not more than 3.0% when calculated as streptomycin base, except that if it is crystalline dihydrostreptomycin sulfate its content of streptomycin sulfate is not more than 1.0%.

§ 146.104 *Streptomycin tablets, dihydrostreptomycin tablets*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin tablets and dihydrostreptomycin tablets is streptomycin or dihydrostreptomycin tableted with or without glucuronolactone and with or without the addition of one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 100 mg. Its moisture content is not more than 3 percent. The streptomycin used conforms to the standards prescribed therefor by § 146.101 (a), except subparagraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146.103, except the standards for sterility and pyrogens. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each streptomycin or dihydrostreptomycin tablet is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of streptomycin or dihydrostreptomycin tablets shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The potency of each tablet of the batch;

(iii) The statement "Expiration date ---------," the blank being filled in with the date which is 18 months after the month during which the batch was certified; and

(iv) If the batch contains the ingredient glucuronolactone, the quantity of such ingredient in each tablet.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----------," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such streptomycin or dihydrostreptomycin tablets, or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of streptomycin or dihydrostreptomycin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, the potency of each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gm. each, packaged in accordance with the requirements of § 146.101 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch of streptomycin or dihydrostreptomycin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $10.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.105 *Streptomycin for topical use; streptomycin with _____ (the blank being filled in with the name of the vehicle if a package combination) for topical use*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin for topical use conforms to all the requirements prescribed by § 146.101 (a) for streptomycin, and may be packaged in combination with a container of a suitable and harmless vehicle.

(b) *Packaging.* The immediate container of streptomycin for topical use shall be of colorless transparent glass so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 20 mg.

(c) *Labeling.* Each package of streptomycin for topical use shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date _____," the blank being filled in with the date which is 24 months after the month during which the batch was certified; and

(iv) The statement "Caution: Not for intravenous or systemic medication."

(2) If it is a package combination, on the immediate container of the vehicle in the combination:

(i) A statement giving the method of dissolving the streptomycin in the vehicle and the statement "The solution may be stored at room temperature for 1 week without significant loss of potency";

(ii) The potency per milliliter after the streptomycin has been dissolved therein; and

(iii) The statement "Caution: Not for intravenous or systemic medication."

(3) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, a statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such streptomycin for topical use, or a reference to a brochure or other printed matter containing such directions and precautions and a statement that such brochure and printed matter will be sent on request.

(4) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such streptomycin for topical use, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of streptomycin for topical use shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of milligrams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, moisture, and pH. If such batch, or any part thereof, is to be packaged with a vehicle, such request shall be accompanied by a statement that such vehicle conforms to the requirements prescribed therefor by this section.

(2) Such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than 50 or more than 100 immediate containers. Such sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) In case of an initial request for the certification of a batch of streptomycin for topical use which is to be packaged in combination with a container of a vehicle, or when any change is made in the composition of such vehicle, such person shall submit in connection with his request five packages of the vehicle included in the combination.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section; $4.00 for each package submitted with the samples in accordance with paragraph (d) (3) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.106 *Streptomycin sulfate solution, dihydrostreptomycin sulfate solution (crystalline dihydrostreptomycin sulfate solution)*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate solution is an aqueous solution of streptomycin sulfate. Dihydrostreptomycin sulfate solution is an aqueous solution of dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate. Such solution conforms to all standards prescribed by § 146.101 for streptomycin sulfate or § 146.103 for dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate, except the limitation on moisture content, and except that:

(1) Its potency is 250 mg. or 500 mg. per milliliter.

(2) It contains one or more suitable and harmless preservatives.

(3) Its pH is not less than 5.0 and not more than 8.0.

(4) It may contain one or more suitable and harmless buffer substances and stabilizing agents.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and

distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless transparent glass closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness, except that if each container is packaged to contain a single dose such container may be a hermetically sealed transparent glass ampul. Each such container shall contain not less than 1 ml. and not more than 50 ml.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each milliliter in the immediate container;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 12 months after the month during which the batch was certified;

(iv) The name and quantity of each preservative used; and

(v) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)," unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for 12 months at room temperature such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams or grams dissolved in each of such packages, the date on which the latest assay of the drug comprising such batch was completed, and if it is crystalline dihydrostreptomycin sulfate solution, the batch mark and (unless it was previously submitted) the date on which the latest assay of the crystalline dihydrostreptomycin sulfate used in making such batch was completed.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, toxicity, pyrogens, histamine content, pH, and streptomycin content, if it is dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate.

(ii) If crystalline dihydrostreptomycin sulfate is used in making the batch; potency and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch, if packaged for dispensing; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The batch, if packaged for repacking or for use as an ingredient in the manufacture of another drug; 5 approximately equal portions of at least 2 ml. each, taken from different parts of such batch and each packaged in a separate container in accordance with the requirements of paragraph (b) of this section.

(iii) If crystalline dihydrostreptomycin sulfate is used in making the batch; 2 immediate containers containing approximately 0.5 gm. each, packaged in accordance with the requirements of § 146.101 (b).

(iv) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (iii) of this paragraph, is required if such result or sample has been previously submitted.

(5) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of the batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) (ii) of this paragraph. From the information required by subparagraph (2) (i) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with regard to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i), (ii) and (5) of this section; $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (iii) and (iv) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.107 *Streptomycin - polymyxin - bacitracin tablets*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin-polymyxin-bacitracin tablets are tablets composed of streptomycin, polymyxin B, and bacitracin, with or without the addition of one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 250 mg. of streptomycin, 200,000 units of polymyxin B, and 5,000 units of bacitracin. Its moisture content is not more than 3%. The streptomycin used conforms to the standards prescribed therefor by § 146.101 (a), except subparagraphs (2) and (4) of that paragraph. The polymyxin used is produced by the growth of Bacillus polymyxa, has a potency of not less than 3,800 units per milligram, and it is nontoxic. The bacitracin used conforms to the standards prescribed therefor by § 146.401 (a), except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 30 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of streptomycin in each tablet of the batch;

(iii) The number of units of polymyxin B in each tablet of the batch;

(iv) The number of units of bacitracin in each tablet of the batch; and

(v) The statement "Expiration date _____," the blank being filled in with the date which is 18 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such tablets, or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of streptomycin-polymyxin-bacitracin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates on which the latest assays of the streptomycin, polymyxin, and bacitracin used in making such batch were completed, the potency of each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency of streptomycin, polymyxin, and bacitracin per tablet, and average moisture.

(ii) The streptomycin used in making the batch; potency, toxicity, histamine, moisture, and pH.

(iii) The polymyxin used in making the batch; potency and toxicity.

(iv) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 30 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The streptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gm. each, packaged in accordance with the requirements of § 146.101 (b).

(iii) The polymyxin used in making the batch; five packages, each containing approximately equal portions of not less than 0.5 gm.

(iv) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 0.5 gm., packaged in accordance with the requirements of § 146.401 (b).

(v) In case of an initial request for certification, each other ingredient used in making the batch; one package of each, containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), and (iv) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of streptomycin-polymyxin-bacitracin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraphs (d) (3) (ii), (iii), (iv), and (v) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.108 *Streptomycin syrup—(a) Standards of identity, strength, quality, and purity.* Streptomycin syrup is streptomycin dissolved in a suitable and harmless diluent that contains one or more suitable and harmless preservatives. Its potency is not less than 50 milligrams per milliliter. The streptomycin used conforms to the standards prescribed therefor by § 146.101 (a), except subparagraphs (2), (4), and (6) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be of colorless, transparent glass, so closed as to be a tight container as defined by the U. S. P. and of such composition that will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of streptomycin in each milliliter of the batch;

(iii) The statement, "Expiration date _____," the blank being filled in with the date which is 12 months after the month during which the batch was certified; and

(iv) The name and quantity of each preservative used.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such drug; or a reference to a brochure or other printed matter containing such directions and precautions and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such syrup, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin used in making the batch was completed, the potency per milliliter of the batch, the quantity of each ingredient used in making the batch, the date on which the latest assay

comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per milliliter.

(ii) The streptomycin used in making the batch; potency, toxicity, histamine content, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gm. each packaged in accordance with the requirements of § 146.101 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of streptomycin syrup under the regulations in this part shall be:

(1) $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (i) and (iii) of this section; $10.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) of this section; and

(2) If the Commissioner considers that investigations other than examinations of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.201 *Aureomycin hydrochloride (aureomycin hydrochloride salt)*—(a) *Standards of identity, strength, quality, and purity.* Aureomycin hydrochloride is the yellow hydrochloride salt or crystalline hydrochloride salt of a kind of aureomycin or a mixture of two or more such salts. It is so purified and dried that:

(1) Its potency is not less than 900 micrograms per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) It contains no histamine or histamine-like substances;

(6) Its moisture content is not more than 2.0%;

(7) Its pH in saturated aqueous solution is 2.3 to 3.3.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is intended for intravenous use, it shall be packaged in immediate containers of colorless, transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain not more than 1.0 gm. unless it is intended solely for veterinary use and is conspicuously so labeled, and each shall contain one or more suitable and harmless diluents, or each shall be packaged in combination with a container of a suitable and harmless diluent.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 12 months, or if it is crystalline aureomycin 36 months, after the month during which the batch was certified;

(iv) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be; and

(v) If it is packaged for intravenous use and contains diluents, the name of each such substance used.

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparation and strength of solutions for different routes of injection and local application;

(iii) The conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions and a statement "Sterile solutions must be injected immediately after preparation";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, crystallinity (if it is the crystalline salt), moisture, and pH. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than eight or more than 15 containers. Such samples shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing five approximately equal portions of at least 0.5 gm. each taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2), (3), and (4) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.202 *Aureomycin ointment (aureomycin hydrochloride ointment)*—(a) *Standards of identity, strength, quality, and purity.* Aureomycin ointment is crystalline aureomycin in a suitable and harmless ointment base. Its moisture content is not more than 1%. The potency is not less than 1 mg. per gram. The aureomycin used conforms to the requirements of § 146.201 (a), except subparagraphs (1), (2), (4), and (5) of that paragraph, but its potency is not less than 750 micrograms per milligram.

Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Aureomycin ointment shall be packaged in collapsible tubes, which shall be well-closed containers as defined by the U. S. P., and shall not be larger than ⅛-ounce size if such ointment is represented for ophthalmic use, and in no case larger than the 2-ounce size, except that if it is labeled solely for hospital use, it may be packaged in immediate containers of glass which meet the test for tight containers as defined by the U. S. P. Each such glass container shall be so sealed that the contents cannot be used without destroying such seal. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of aureomycin ointment shall bear on its label or labeling as hereinafter indicated:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of milligrams per gram in the batch; and

(iii) The statement "Expiration date _____," the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such ointment; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such ointment, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aureomycin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the aureomycin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The aureomycin used in making the batch; potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than five packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The aureomycin used in making the batch; ten packages, containing approximately equal portions of not less than 60 mg. each, packaged in accordance with the requirements of § 146.201 (b).

(iii) In case of an initial request for certification, the ingredients used in making the ointment base of the batch; one package of each containing approximately 200 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of aureomycin ointment under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.203 *Aureomycin troches (aureomycin hydrochloride troches)*—(a) *Standards of identity, strength, quality, and purity.* Aureomycin troches are troches composed of crystalline aureomycin and one or more suitable and harmless diluents, binders, and lubricants, with or without one or more suitable and harmless colorings and flavorings. The potency of each troche is not less than 5 mg.; the moisture content is not more than 2%. The aureomycin used conforms to the requirements of § 146.201 (a), except subparagraphs (1), (2), (4), and (5) of § 146.201 (a), but its potency is not less than 750 micrograms per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each aureomycin troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of aureomycin troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each troche of the batch; and

(iii) The statement "Expiration date _____", the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Caution: To be dispensed only by or on the prescription of a ----------", the blank being filled in with the word "physician" or "dentist" or both, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such troches; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aureomycin troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the aureomycin used in making such batch was completed, the number of milligrams in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per troche and average moisture.

(ii) The aureomycin used in making the batch; potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one troche for each 5,000 troches in the batch, but in no case less than 20 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made that the quantities made during the intervals are approximately equal.

(ii) The aureomycin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 mg., packaged in accordance with the requirements of § 146.201 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch of aureomycin troches under the regulations in this part shall be:

(1) $1.00 for each troche in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.204 *Aureomycin capsules (aureomycin hydrochloride capsules)* — (a) *Standards of identity, strength, quality, and purity.* Aureomycin capsules are capsules composed of crystalline aureomycin, with or without one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings, enclosed in a hard gelatin capsule. The potency of each capsule is not less than 50 mg. Its moisture content is not more than 2 percent. The aureomycin used conforms to the requirements of § 146.201 (a), except subparagraphs (2), (4), and (5) of § 146.201 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each aureomycin capsule is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the capsules by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of aureomycin capsules shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each capsule of the batch;

(iii) The statement "Expiration date ----," the blank being filled in with the date which is 36 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----------," the blank being filled in with the words "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such aureomycin capsules; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such aureomycin capsules, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including those from any buffer substance present.

If two or more such immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aureomycin capsules shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the aureomycin used in making such batch was completed, the number of milligrams in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule and average moisture.

(ii) The aureomycin used in making the batch; potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of preparation that the quantities encapsulated during the intervals are approximately equal.

(ii) The aureomycin used in making the batch; ten packages, each contain-

ing approximately equal portions of not less than 60 mg., packaged in accordance with the requirements of § 146.201 (b).

(iii) In case of an initial request for certification, each buffer substance, diluent, binder, lubricant, coloring, and flavoring used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of aureomycin capsules under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.205 *Aureomycin powder (aureomycin hydrochloride powder)*—(a) *Standards of identity, strength, quality, and purity.* Aureomycin powder is crystalline aureomycin with or without suitable and harmless buffer substances, diluents, colorings, and flavorings. Its content of aureomycin is not less than 15 mg. per gram of powder. Its moisture content is not more than 2 percent. The aureomycin used conforms to the requirements of § 146.201 (a), except subparagraphs (2), (4), and (5) of § 146.201 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container of aureomycin powder shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of aureomycin powder shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams per gram in the immediate container;

(iii) The statement "Expiration date _____," the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the words "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such aureomycin powder; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such aureomycin powder, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including those from any buffer substance present.

If two or more such immediate containers are in such package the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aureomycin powder shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the aureomycin used in making such batch was completed, the number of milligrams in each immediate container, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The aureomycin used in making the batch; potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 containers in the batch, but in no case less than 20 such containers or more than 100 immediate containers, unless each such container is packaged to contain more than 1 gm., in which case the sample shall consist of 1 gm. for each 5,000 immediate containers in the batch, but in no case less than 20 gm. or more than 100 gm. Such samples shall be collected by taking single immediate containers or 1-gm. portions at such intervals throughout the entire time the containers are being filled that the quantities made during the intervals are approximately equal.

(ii) The aureomycin used in making the batch; ten packages, each containing approximately equal portions of not less than 60 mg., packaged in accordance with the requirements of § 146.201 (b).

(iii) In case of an initial request for certification, each buffer substance, diluent, coloring, and flavoring used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of aureomycin powder under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.206 *Aureomycin ophthalmic (aureomycin hydrochloride ophthalmic)*—(a) *Standards of identity, strength, quality, and purity.* Aureomycin ophthalmic is crystalline aureomycin with or without one or more suitable and harmless buffers and diluents. Its moisture content is not more than 5%. The aureomycin is of such quantity that when dissolved as directed the potency of such solution is not less than 1,000 micrograms per milliliter and maintains its labeled potency after it has been kept for 2 days at a temperature of 15° C. (59° F.). Such solution has a pH of 8.2, ± 0.2. The aureomycin used conforms to the requirements of § 146.201 (a) except subparagraphs (2), (4), and (5) of § 146.201 (a). Each buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container of aureomycin ophthalmic shall be a tight container as defined by the

U. S. P.; its closure shall be one through which a hypodermic needle cannot be introduced; and the container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 5 mg., and each may be packaged in combination with a container of the solvent, distilled water U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date ---------," the blank being filled in with the date which is 36 months after the month during which the batch was certified; and

(iv) If it is packaged in combination with a container of a solvent, the statement "Warning—Not for injection."

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use, and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----------," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is conspicuously so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such aureomycin ophthalmic; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such aureomycin ophthalmic, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aureomycin ophthalmic shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless previously submitted) the date on which the latest assay of the aureomycin used in making such batch was completed, the number of milligrams in each immediate container, the quantity of each buffer and diluent used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each buffer and diluent used in making the batch conform to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The aureomycin used in making the batch; potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 20 immediate containers or more than 100 immediate containers, collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The aureomycin used in making the batch; ten packages, each containing approximately equal portions of not less than 60 mg. packaged in accordance with the requirements of § 146.201 (b).

(iii) In case of an initial request for certification, each buffer and diluent used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i), $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.207 *Aureomycin tablets (aureomycin hydrochloride tablets).* Aureomycin tablets conform to all requirements prescribed by § 146.204 for aureomycin capsules, and are subject to all procedures prescribed by § 146.204 for aureomycin capsules, but if such tablets are represented for vaginal use the potency of each such tablet shall not be less than 250 mg.

§ 146.208 *Aureomycin otic (aureomycin hydrochloride otic).*—(a) *Standards of identity, strength, quality, and purity.* Aureomycin otic is a packaged combination of one immediate container of crystalline aureomycin and one immediate container of a suitable and harmless solution. The aureomycin is of such quantity that when dissolved as directed the potency of such solution is not less than 5 mg. per milliliter after it has been kept for 7 days at a temperature of 15° C. (59° F.). The aureomycin used conforms to the requirements of § 146.201 (a), except subparagraphs (2), (4), and (5) of § 146.201 (a). Each substance used in the preparation of the solution contained in the packaged combination, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of aureomycin otic shall bear on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and on the immediate container of the aureomycin:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date ---------," the blank being filled in with the date which is 24 months after the month during which the batch was certified; and

(iv) The statement "Warning—Not for injection."

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination:

(i) A statement giving the method of dissolving the aureomycin in the solution;

(ii) The potency per milliliter after the aureomycin has been dissolved therein; and

(iii) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions, and the statement "The solution may be kept in a refrigerator for 1 week without significant loss of potency."

(3) On the outside wrapper or container:

(i) The statement "Caution: To be dispensed only by or on the prescription of a physician"; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of aureomycin otic; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent to physicians on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of aureomycin otic shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of milligrams in each immediate container thereof, the date on which the latest assay of the batch was completed, the batch mark, and (unless it was previously submitted) the date on which the latest assay of the aureomycin used in making such batch was completed, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The solution after the aureomycin has been dissolved therein; potency.

(iii) The aureomycin used in making the batch; potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 20 packages or more than 100 packages, collected by taking a single package at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The aureomycin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 mg., packaged in accordance with the requirements of § 146.201 (b).

(iii) In case of an initial request for certification, or when any change is made in composition of such solution; 5 packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigation.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.209 *Aureomycin dental cones (aureomycin hydrochloride dental cones).* Aureomycin dental cones conform to all requirements prescribed by § 146.203 for aureomycin troches, and are subject to all procedures prescribed by § 146.203 for aureomycin troches, except that they may contain a suitable local anesthetic.

§ 146.210 *Aureomycin dental paste (aureomycin hydrochloride dental paste).* Aureomycin dental paste conforms to all requirements prescribed by § 146.202 for aureomycin ointment, and is subject to all procedures prescribed by § 146.202 for aureomycin ointment, except that:

(a) Its potency is not less than 30 mg. per gram.

(b) Its moisture content is not more than 3%.

(c) It contains one or more suitable and harmless binders, and it may contain one or more suitable and harmless colorings and flavorings.

(d) It is packaged in immediate containers of glass which meet the tests for tight containers as defined by the U. S. P.

§ 146.301 *Chloramphenicol* — (a) *Standards of identity, strength, quality, and purity.* Chloramphenicol is a white to grayish-white or yellowish-white crystalline powder, occurring as needles or elongated plates. It is neutral, slightly soluble in water, but freely soluble in alcohol. It has the chemical formula D-(—)-*threo*-1-*p* - nitrophenyl - 2 - dichloracetamido-1,3-propanediol. It is so purified and dried that:

(1) Its potency is not less than 900 micrograms per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) It contains no histamine nor histamine-like substances;

(6) Its pH in saturated aqueous solution is not less than 4.5 and not more than 7.5;

(7) Its specific rotation in absolute ethanol at 20° C. is $+20°\pm1.5°$, and at 25° C. is $+18.5°\pm1.5°$.

(8) Its melting point is 151° C.±2°.

(9) Its extinction coefficient $E^{1\%}_{1\ cm.}$ is 298±9 at 278 mμ when measured in aqueous solution.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain not more than 1.0 gm., and each may be packaged in combination with a suitable and harmless diluent.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of grams in the immediate container;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 36 months after the month during which the batch was certified; and

(iv) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparation and strength of solutions for different routes of injection and local application;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of chloramphenicol shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of grams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine, crystallinity, pH, specific rotation, melting point, and extinction coefficient. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with

his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than 8 immediate containers or more than 15 immediate containers.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing ten approximately equal portions of at least 300 mg. each, taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches of chloramphenicol or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2), (3), and (4) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.302 *Chloramphenicol capsules*—(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol capsules are capsules composed of chloramphenicol, with or without the addition of one or more suitable and harmless diluents, lubricants, colorings, and flavorings. The potency of each capsule is not less than 50 mg. The chloramphenicol used conforms to the requirements of § 146.301 (a), except subparagraphs (2), (4), (5), and (6) of § 146.301 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each chloramphenicol capsule is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of chloramphenicol capsules shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each capsule of the batch; and

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 36 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----------," the blank being filled in with the words "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such chloramphenicol capsules; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions, adequate for the use of such chloramphenicol capsules, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of chloramphenicol capsules shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chloramphenicol used in making such batch was completed, the number of milligrams in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule.

(ii) The chloramphenicol used in making the batch; potency, toxicity, crystallinity, specific rotation, melting point, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of preparation that the quantities encapsulated during the intervals are approximately equal.

(ii) The chloramphenicol used in making the batch; ten packages, each containing approximately equal portions of not less than 300 mg. each, packaged in accordance with the requirements of § 146.301 (b).

(iii) In case of an initial request for certification, each diluent, lubricant, coloring, and flavoring used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of chloramphenicol capsules under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsule and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.401 *Bacitracin*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin is a white to brown, neutral water-soluble polypeptide. It is so purified and dried that:

(1) Its potency is not less than 40 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 5%;

(6) Its pH in aqueous solution of 10,000 units per milliliter is not less than 5.5 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for topical use, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain not more than 50,000 units and may be packaged in combination with a container of the solvent, water for injection U. S. P., physiological salt solution U. S. P., or with a container of an aqueous solution of a suitable local anesthetic.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 18 months after the month during which the batch was certified; and

(iv) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," as the case may be, when packaged for repacking or for use as an ingredient in the manufacture of another drug.

(2) On the circular or other labeling within or attached to the package, if it is packaged for topical use, adequate directions for use and warnings as required by section 502 (f) of the act, including:

(i) Clinical indications;

(ii) Dosage and administration, including method of preparation and strength of solutions for local application;

(iii) The conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions, and the statement "Sterile solution may be kept in refrigerator for one week without significant loss of potency";

(iv) Contraindications; and

(v) Untoward effects that may accompany administration, including sensitization.

If two or more immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of bacitracin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, and pH. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for topical use such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than six immediate containers or more than 13 immediate containers, except if the total potency contained in such immediate containers is less than 100,000 units and a sample of such batch has not been previously submitted under subparagraph (3) or (4) of this paragraph, such person shall submit in addition to the quantity specified herein one other container which contains a quantity sufficient to make the total potency of all containers in the sample equal to approximately 100,000 units.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing six approximately equal portions of at least 500 mg. each, taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraphs (d) (2), (3), and (4) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.402 *Bacitracin ointment*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin ointment is bacitracin in a suitable and harmless ointment base. Its moisture content is not more than 1 percent. Its potency is not less than 500 units per gram. The bacitracin used conforms to the requirements of § 146.401 (a), except subparagraphs (1), (2), and (4) of § 146.401 (a), but its potency is not less than 30 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Bacitracin ointment shall be packaged in collapsible tubes, which shall be well-closed containers as defined by the U. S. P. and which shall not be larger than the 2-ounce size, except if it is labeled solely for hospital use; but in no case shall it be packaged in containers other than collapsible tubes if it is represented for ophthalmic use, and such tubes shall not be larger than the ⅛-ounce size. If it is labeled solely for hospital use and it is packaged in immediate containers of glass, such containers shall meet the test for tight containers as defined by the U. S. P. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of bacitracin ointment shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units per gram of the batch; and

(iii) The statement "Expiration date ---------," the blank being filled in with the date which is not more than 18 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use, and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ---------," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless the drug is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such ointment; or a reference to a brochure or other printed matter containing such directions and precautions, and a

statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if the drug is intended solely for veterinary use, directions and precautions adequate for the use of such ointment, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of bacitracin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 500 mg., packaged in accordance with the requirements of § 146.401 (b).

(iii) In case of an initial request for certification, the ingredients used in making the ointment base of the batch; one package of each containing approximately 200 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of bacitracin ointment under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.403 *Bacitracin tablets*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin tablets are tablets composed of bacitracin with or without the addition of one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 1,000 units nor more than 10,000 units. Its moisture content is not more than 5 percent. Unless it is represented to be used for inhalation therapy, the bacitracin used conforms to the requirements of § 146.401 (a), except subparagraphs (1), (2), and (4) of that paragraph, but in no case is its potency less than 30 units per milligram. If it is represented to be used for inhalation therapy, the bacitracin used conforms to the requirements of §146.401 (a), except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each bacitracin tablet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of bacitracin tablets shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) Unless it is intended solely for veterinary use and is conspicuously so labeled, the statement "Caution: To be dispensed only by or on the prescription of a ----------," the blank being filled in with the words "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) Unless it is intended solely for veterinary use and is so labeled, a reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such bacitracin tablets; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure or printed matter will be sent on request.

(3) On the circular or other labeling within or attached to the package, if it is intended solely for veterinary use, directions and precautions adequate for the use of such bacitracin tablets, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of such circulars or other labeling shall not be less than the number of such containers.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of bacitracin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less

than 500 mg. each, packaged in accordance with the requirements of § 146.401 (b).

(iii) In case of an initial request for certification, each buffer substance, diluent, binder, lubricant, coloring, and flavoring used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of bacitracin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.404 *Bacitracin troches*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin troches are troches composed of bacitracin, with or without ethyl aminobenzoate and with one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each troche is not less than 500 units. Its moisture content is not more than 5 percent. The bacitracin used conforms to the requirements of § 146.401 (a), except subparagraphs (1), (2), and (4) of § 146.401 (a), but its potency is not less than 30 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each bacitracin troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of bacitracin troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of bacitracin and if it contains ethyl aminobenzoate, the quantity of such ingredient in each troche of the batch; and

(iii) The statement "Expiration date _____," the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container:

(i) The statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or both, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of such troches; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of bacitracin troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the number of units in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per troche and average moisture.

(ii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one troche for each 5,000 troches in the batch, but in no case less than 20 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made, that the quantities made during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 500 mg., packaged in accordance with the requirements of § 146.401 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 gm.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch of bacitracin troches under the regulations in this part shall be:

(1) $1.00 for each troche in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.405 *Bacitracin with vasoconstrictor; bacitracin with _____ (the blank being filled in with the common or usual name of the vasoconstrictor)*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin with vasoconstrictor is a dry mixture of bacitracin and a suitable vasoconstrictor, with or without suitable and harmless buffer substances, preservatives, colorings, and flavorings, or it is a packaged combination of one immediate container of bacitracin and one immediate container of a solution of a suitable vasoconstrictor, with or without suitable and harmless buffer substances, preservatives, colorings, and flavorings. The bacitracin is of such quantity that when dissolved as directed the potency of such solution is not less than 200 units per milliliter, and maintains its labeled potency after it has been kept for 7 days at a temperature of 15° C. (59° F.). Such solution is isotonic, and has a pH of 6.0, ±0.5. The moisture content of the dry mixture of bacitracin with vasoconstrictor is not more than 5 percent. The bacitracin used conforms to the requirements of § 146.401 (a), except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate container of the dry mixture of bacitracin with vasoconstrictor may be packaged in combina-

tion with an immediate container of a suitable diluent.

(c) *Labeling.* Each package of bacitracin with vasoconstrictor shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the bacitracin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) If it is a packaged combination of one immediate container of bacitracin and one immediate container of a vasoconstrictor, the statement "Expiration date _____," the blank being filled in with the date which is 18 months after the month during which the batch was certified. If it is the dry mixture of bacitracin with vasoconstrictor, the statement "Expiration date _____," the blank being filled in with the date which is 12 months after the month during which the batch was certified.

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination:

(i) A statement giving the method of dissolving the bacitracin and, if it is not a packaged combination, a statement that distilled water U. S. P. should be used;

(ii) The potency per milliliter after the bacitracin has been dissolved therein;

(iii) The statement "Warning: Not for injection"; and

(iv) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions, and a statement "The solution may be kept at room temperature for 1 week without significant loss of potency."

(3) On the outside wrapper or container, unless it is intended solely for veterinary use and is conspicuously so labeled:

(i) The statement "Caution: To be dispensed only by or on the prescription of a _____," the blank being filled in with the word "physician" or "dentist" or "veterinarian" or with any combination of two or all of these words, as the case may be; and

(ii) A reference specifically identifying a readily available medical publication containing directions and precautions (including contraindications and possible sensitization) adequate for the use of bacitracin with vasoconstrictor; or a reference to a brochure or other printed matter containing such directions and precautions, and a statement that such brochure and printed matter will be sent on request.

(4) If intended solely for veterinary use, directions and precautions adequate for the use of such bacitracin with vasoconstrictor, including:

(i) Clinical indications;

(ii) Dosage and administration;

(iii) Contraindications; and

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2, a person who requests certification of a batch of bacitracin with vasoconstrictor shall submit with his request a statement showing the batch mark, the number of packages in such batch, the number of units in each immediate container, and (unless it was previously submitted) the date on which the latest assay of the bacitracin included in such batch was completed, the quantity of each ingredient used in making the batch of the dry mixture of bacitracin with vasoconstrictor, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The bacitracin included in the packaged combination and the bacitracin used in making the batch of the dry mixture of bacitracin with vasoconstrictor; potency, toxicity, moisture, and pH.

(ii) The solution after the bacitracin has been dissolved therein; potency.

(iii) The batch of the dry mixture of bacitracin with vasoconstrictor; potency and moisture.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The bacitracin for inclusion in the packaged combination of bacitracin with vasoconstrictor; one immediate container for each 5,000 immediate containers in the batch but in no case less than 20 immediate containers or more than 100 immediate containers, if the bacitracin used has been previously submitted, and not less than 40 immediate containers or more than 100 immediate containers if the bacitracin used has not been previously submitted, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The dry mixture of bacitracin with vasoconstrictor; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 20 immediate containers or more than 100 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(iii) The bacitracin used in making the batch of the dry mixture of bacitracin with vasoconstrictor; six packages, each containing approximately equal portions of not less than 500 mg. each, packaged in accordance with the requirements of § 146.401 (b).

(iv) In case of an initial request for certification of a batch of a dry mixture of bacitracin with vasoconstrictor, each other substance used in making the batch; one package of each containing approximately 5 gm.

(v) In case of an initial request for certification of the packaged combination of bacitracin with vasoconstrictor, or when any change is made in the composition of such solution; five packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (i) of this paragraph, and no samples referred to in subparagraph (3) (i) and (iii) of this paragraph, are required if such result or samples has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of bacitracin with vasoconstrictor under the regulations in this part shall be:

(1) $1.00 for each immediate container submitted in accordance with paragraph (d) (3) (i) and (ii) of this section, or $2.00 if no such sample is submitted; $4.00 for each package submitted in accordance with paragraph (d) (3) (iii), (iv), and (v) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d).

§ 146.406 *Bacitracin-tyrothricin troches.* (a) Bacitracin-tyrothricin troches conform to all requirements prescribed by § 146.404 for bacitracin troches and are subject to all procedures prescribed by § 146.404 for bacitracin troches except that:

(1) Each troche contains not less than 50 units of bacitracin.

(2) Each troche contains not less than 1 mg. of tyrothricin.

(3) Each troche may be tableted with or without ethyl aminobenzoate.

(b) In lieu of the directions prescribed for bacitracin troches by § 146.404 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin and the number of milligrams of tyrothricin and ethyl aminobenzoate in each troche of the batch.

[F. R. Doc. 50-12593; Filed, Dec. 29, 1950; 8:53 a. m.]

TITLE 24—HOUSING AND HOUSING CREDIT

Chapter IV—Federal National Mortgage Association

PART 400—MORTGAGE PURCHASES, SERVICING AND SALES

Sec.

SUBPART A—MORTGAGE PURCHASE PROGRAM

AUTHORITY: §§ 400.1 to 400.400 issued under sec. 301, 48 Stat. 1252, as amended; 12 U. S. C. 1716. Reorg. Plan No. 22 of 1950, 15 F. R. 4365.

§ 400.1 *General.* Federal National Mortgage Association (hereinafter called "FNMA") is a corporate instrumentality of the United States, the capital stock of which is wholly-owned by the Housing and Home Finance Administrator. Its principal powers are prescribed by Title III of the National Housing Act, as amended (hereinafter called the "NH Act"). FNMA provides a market for the purchase and sale of certain real estate mortgage loans. It purchases on an over-the-counter basis mortgage loans guaranteed under certain provisions of the Servicemen's Readjustment Act of 1944, as amended (hereinafter called the "SR Act"), or insured under certain provisions of the NH Act. The mortgages which FNMA owns are made available for sale to eligible investors.

§ 400.2 *Purchase price.* The association will pay for each eligible mortgage purchased by it an amount equal to the unpaid principal balance thereof plus accrued and unpaid interest at the date of disbursement of the purchase price.

§ 400.3 *Sales price.* The prices at which mortgages owned by FNMA are currently made available for sale may be obtained by application to FNMA's local offices.

SUBPART A—MORTGAGE PURCHASE PROGRAM

§ 400.100 *Eligibility.* This subpart contains the principal requirements which any mortgage and any mortgage seller must meet if the mortgage is to be eligible for purchase by FNMA.

ELIGIBLE VA-GUARANTEED MORTGAGES

§ 400.101 *Guaranty.* Any mortgage guaranteed by the Administrator of Veterans' Affairs (hereinafter called a "VA-guaranteed mortgage") must have been guaranteed pursuant to sections 501, 502, or 505 (a) of the SR Act.

§ 400.102 *VA prior approval.* VA-guaranteed mortgages in connection with which the credit and security instruments are dated on or after March 1, 1950, must have been processed through the VA prior approval procedure. This requirement does not apply to any mortgage covered by a commitment contract executed by FNMA prior to March 1, 1950.

§ 400.103 *Extent of guaranty for single-family dwelling units.* If the improvements on the mortgaged premises comprise one single-family dwelling unit, the original principal amount of the mortgage must have been guaranteed: (a) in the case of a section 501 mortgage, to the extent of 60 percent, except that when the mortgage (1) is covered by a commitment contract executed by FNMA prior to March 21, 1950, or (2) is covered by a FNMA purchase contract, whenever executed, and the guaranty became fully effective prior to November 1, 1950, the mortgage must have been guaranteed to the extent of not less than 50 percent or $4,000, whichever is less. The requirement in (2) above that the guaranty must have become fully effective prior to November 1, 1950, will be waived, however, if the seller establishes to the satisfaction of FNMA that the application for loan guaranty (VA Form 4–1802), or loan report (VA Form 4–1820), upon which the related VA certificate of commitment (VA Form 4–1866) was issued, was filed with the Veterans Administration prior to April 20, 1950); (b) in the case of a section 502 mortgage, to the extent of 50 percent or $4,000, whichever is less.

§ 400.104 *Extent of guaranty for multiple-family dwelling units.* (a) If the improvements on the mortgaged premises comprise two or more single-family dwelling units, the original principal amount of the mortgage must not have exceeded the orgiinal amount of the guaranty, plus 50 percent of the purchase price or cost of the premises, except that if (1) the mortgage is covered by a commitment contract executed by FNMA prior to March 21, 1950, or (2) if the seller establishes to the satisfaction of FNMA that the application or loan report, upon which the related VA certificate of comitment was issued, was filed with Veterans Administration prior to April 20, 1950, the original principal amount of the mortgage must not have exceeded the original amount of the guaranty, plus 60 percent of the purchase price or cost of the premises.

(b) This section contemplates that the mortgagors, without exception (except spouses), will be veterans whose entitlement to guaranty, without reduction resulting from prior use of all or a portion thereof, will be employed to the fullest extent provided for by the SR Act for the purposes of the mortgage loan or loans under consideration; and it also contemplates, when there is more than one veteran-mortgagor, that all such veteran-mortgagors will be jointly and severally liable for the mortgage debt. Included in this section are instances of a single multi-family building containing two or more single-family dwelling units and also instances of a single parcel or realty upon which the improvements consist of two or more family residences. The officers of FNMA are authorized to consider any case in which joint liability is not present.

§ 400.105 *Section 502 mortgages.* The mortgaged premises must be improved by a farm residence, and the original principal amount of the mortgage must not have exceeded the purchase price or cost of the premises (computed without the inclusion of the VA-appraised reasonable value of live stock, farm machinery and automotive or other farm equipment, if any).

§ 400.106 *Section 505 (a) second mortgage.* The original principal amount of the nortgage must not have exceeded 20 percent of the purchase price or cost of the mortgaged premises; the sum of its original principal amount and the original amount of the related FHA first mortgage must not have exceeded $10,000 for each single-family dwelling unit covered thereby; it must be guaranteed 100 percent by VA. FNMA purchases VA-guaranteed section 505 (a) mortgages only when delivered concurrently with the related FHA first mortgage or if the first mortgage is then owned by FNMA. Both mortgages must be eligible for purchase.

§ 400.107 *Maturity.* Each VA mortgage must mature not more than 25 years from the date of the note, or the date of assumption of the mortgage debt by the veteran-borrower for whom the mortgage loan is guaranteed: except, that the term may be 30 years as to any mortgage that is guaranteed by VA to the extent of 60 percent.

§ 400.108 *Application of gratuity.* The VA gratuity payment of 4 percent of the original amount of the guaranty, or that portion thereof to which the mortgagor may be entitled after reduction or offset by reason of any indebtedness of the mortgagor to VA, if received by seller prior to the delivery of the mortgage to FNMA, must have been credited upon the loan in the manner required by the regulations of the Veterans' Administration; if not received prior to the delivery of the mortgage to FNMA, seller must agree to remit the amount of the gratuity to FNMA promptly after receipt thereof.

§ 400.109 *Closing costs.* The original principal amount of a guaranteed mortgage, in connection with which the credit and security instruments are dated on or after March 1, 1950, may not exceed the purchase price or cost of the property computed without the inclusion of closing costs. This requirement does not apply to any mortgage covered by a commitment contract executed by FNMA prior to March 1, 1950.

§ 400.110 *Date of first installment.* The period of time between the date of a note, or the date of assumption of the mortgage debt by the veteran-borrower for whom the mortgage is guaranteed, and the due date of the first installment of principal and interest shall not exceed: (a) Six months, if the amortization installments are payable monthly or quarterly, except that if in such cases the seller establishes to the satisfaction of FNMA that the veteran-borrower executed the note or assumed the mortgage debt prior to the commencement of construction, the period shall not exceed twelve months; (b) twelve months, if the amortization installments are payable semi-annually or annually.

ELIGIBLE FHA-INSURED MORTGAGES

§ 400.150 *Insurance.* Any mortgage insured by the Federal Housing Commissioner (hereinafter called "FHA-insured mortgage") must have been insured pursuant to sections 8, 203, 603 or 803 of the NH Act.

VA-GUARANTEED AND FHA-INSURED MORTGAGES

§ 400.170 *Maximum loan.* The original principal amount of any mortgage must not have exceeded $10,000 for each single-family dwelling unit covered thereby.

§ 400.171 *Interest.* Mortgages offered to FNMA for purchase must bear interest at not less than the following rates: FHA-insured section 203 mortgages, 4¼ percent per annum; all other mortgages, 4 percent per annum. Interest accruing to the day which precedes by one regular installment period the due date of the first full installment of principal and interest, shall have been paid by or for the account of the mortgagor.

§ 400.172 *Amortization.* Each mortgage, except VA-guaranteed section 502 mortgages, must provide for amortization thereof by the payment of equal monthly installments applicable to interest and principal, payable on the first day of each month. The installments in VA-guaranteed section 502 mortgages may be payable on a monthly, quarterly, semi-annual or annual basis. Each mortgage must provide for additional periodic payments to cover ground rents, taxes, special assessments, other levies and charges, fire and other hazard insurance premiums, and mortgage insurance premiums, if any.

§ 400.173 *Period of eligibility.* Any mortgage purchased by FNMA pursuant to a purchase contract, must have been initially guaranteed or insured subsequent to February 28, 1950, and such guaranty or insurance must have become fully effective not less than two (2) months nor more than twelve (12) months prior to the date of delivery of the mortgage to FNMA for purchase, except that a VA-guaranteed section 505 (a) mortgage is not subject to the two months' waiting period or the cut-off date of February 28, 1950.

§ 400.174 *Location of premises.* The mortgaged premises must be located within a radius of 200 miles of the principal office of the seller, or of a branch office of seller which FNMA has determined is adequately equipped to service mortgages; or of an office of a bona fide agent of seller if both agent and office have been approved by FNMA.

§ 400.175 *Loan documents and related instruments.* (a) The notes and security instruments must be on standard forms approved by FNMA, published by FHA or VA and obtainable from their respective field offices.

(b) As a condition of the delivery of any mortgage to FNMA, the seller must have executed a purchasing and servicing agreement, purchase contract, seller's statement, and a seller's certificate, each in form prescribed by FNMA. Seller must comply with all the requirements of such documents and must also comply with such further purchase requirements as FNMA may, from time to time, prescribe.

§ 400.176 *Title evidence.* The types of title evidence which will be acceptable to FNMA are enumerated and described in the purchasing and servicing agreement.

§ 400.177 *Additional requirements.* When a mortgage is delivered to FNMA: All payments must be current; seller will have complied with the NH Act, and the SR Act, if applicable, and the rules and regulations respectively promulgated thereunder by the Administrator of Veterans Affairs and the Federal Housing Commissioner; the guaranty or insurance will be fully effective; the improvements will be undamaged and in all respects ready for occupancy; the seller must have no knowledge of any existing condition affecting the mortgagor or his affairs which in the opinion of the seller will cause the mortgage to become delinquent.

ELIGIBLE SELLERS

§ 400.190 *VA-guaranteed mortgages.* In order to be eligible to sell any VA-guaranteed mortgage to FNMA a lender must be within any of the following three classifications:

(a) Any lender that is classified by VA as a "supervised lender" under section 500 (d) of the SR Act, including any National bank, State bank, private bank, building and loan association, insurance company, credit union, or mortgage and loan company, which is subject to examination and supervision by an Agency of the United States or of any State or Territory, including the District of Columbia.

(b) Any lender that is approved by FNMA for the sale of FHA-insured mortgages to FNMA.

(c) Any lender satisfactory to FNMA that is adequately equipped to service mortgages and has a net worth of not less than $50,000. (Lenders that do not qualify under the two foregoing classifications may apply to FNMA for designation as an eligible seller; the letter of application should describe in careful detail the lender's servicing facilities and should transmit a recent financial statement.)

§ 400.191 *FHA-insured mortgages.* Any FHA-approved mortgagee is an eligible seller and may offer eligible mortgages to FNMA for purchase. The term "FHA-approved mortgagee," as used herein, means an institution, agency, or organization that has been approved by FHA as the holder of, and the original lender upon, a mortgage insured pursuant to the provisions of Title I, Title II, Title VI, or Title VIII of the NH Act. Such term does not include a mortgagee that has been approved on the basis of being a duly authorized loan correspondent of an approved mortgagee which has qualified with FHA to originate loans under the NH Act.

SUBPART B—MORTGAGE SERVICING PROGRAM

§ 400.200 *Mortgage servicing.* Sellers are required to service all VA-guaranteed and FHA-insured mortgages purchased by FNMA, except FHA-insured section 207, 608 and 803 loans (which are serviced by FNMA), but the seller is not required to foreclose or bear any part of foreclosure expenses. The compensation paid to servicers for the performance of their servicing duties is as set forth in the purchasing and servicing agreement. Purchasing and servicing agreements are cancellable in whole or in part upon thirty days' written notice at the option of FNMA.

SUBPART C—MORTGAGE SALES PROGRAM

§ 400.300 *Eligible purchasers.* (a) Mortgages purchased by FNMA are made available for sale to eligible purchasers.

(b) Any investor that, in the opinion of FNMA, is qualified to service the mortgage is eligible to purchase VA-guaranteed mortgages.

(c) Any investor that is an FHA-approved mortgagee is eligible to purchase FHA-insured mortgages.

§ 400.301 *Procedures.* (a) Lists of mortgages (by State, county and city) owned and available for sale may be obtained by prospective purchasers upon application to FNMA.

(b) Prospective purchasers may select mortgages in which they are interested from the prepared lists. Any number of mortgages may be selected by a prospective purchaser to be included in an option or sale; and any or all of the mortgages included in an option may be made the subject of a sale.

(c) FNMA grants options for reasonable periods during which the mortgaged properties may be inspected and the mortgage documents examined at FNMA's local offices. Since existing servicing arrangements that are transferred with the mortgages are cancellable on thirty days' notice at the option of the owner of the mortgage, purchasers will always be able to effect their own arrangements for future servicing. FNMA will endeavor to comply with the wishes of purchasers with respect to arranging closing schedules and other matters incident to consummating sales.

(d) In instances in which both the FHA-insured first mortgage and VA-guaranteed section 505 (a) second mortgage covering the same property are owned by FNMA, sale will be made only on the basis that the investor will purchase both mortgages as a package.

EXCEPTIONS

§ 400.400 *Exceptions.* In the conduct of its affairs, in individual cases or classes of cases, FNMA reserves the right to alter or waive any of the requirements contained in this part or to impose other and additional requirements, and it further reserves the right to rescind or amend any or all of the regulations in this part.

J. S. BAUGHMAN,
President,
Federal National Mortgage Association.

[F. R. Doc. 50-12464; Filed, Dec. 29, 1950; 8:46 a. m.]

TITLE 26—INTERNAL REVENUE

Chapter I—Bureau of Internal Revenue, Department of the Treasury

Subchapter D—Employment Taxes

[T. D. 5823]

[Regs. 128]

PART 408—EMPLOYEE TAX AND EMPLOYER TAX UNDER THE FEDERAL INSURANCE CONTRIBUTIONS ACT; APPLICABLE ON AND AFTER JANUARY 1, 1951

Waiver under section 1426 (b) (9) (B) and section 1426 (l) of the Internal Revenue Code of exemption from Federal Insurance Contributions Act taxes by an organization exempt from income tax under section 101 (6) of the Internal Revenue Code.

PARAGRAPH 1. On November 17, 1950, there was published in the FEDERAL REGISTER (15 F. R. 7838) notice of proposed rule making regarding the proposed regulations relating to section 1426 (b) (9) (B) and section 1426 (l) of the Internal Revenue Code, added by section 204 of Social Security Act Amendments of 1950. No objection to the rules proposed having been received, the regulations set forth below are hereby adopted:

Sec.
408.1 Scope of part.
408.2 Who may waive exemption.
408.3 Form and effect of waiver.
408.4 Termination of waiver by organization.
408.5 Termination of waiver by Commissioner.

AUTHORITY: §§ 408.1 to 408.5 issued under 53 Stat. 178, 26 U. S. C. 1429.

SECTION 204 (a), (e), AND (g) OF THE SOCIAL SECURITY ACT AMENDMENTS OF 1950

DEFINITION OF EMPLOYMENT

(a) Effective January 1, 1951, section 1426 (b) of the Internal Revenue Code is amended to read as follows:

(b) *Employment.* The term "employment" means * * * any service, of whatever nature, performed after 1950 * * * by an employee for the person employing him * * * ; except that * * * such term shall not include—

* * * * *

(9) (A) Service performed by a duly ordained, commissioned, or licensed minister of a church in the exercise of his ministry or by a member of a religious order in the exercise of duties required by such order;

(B) Service performed in the employ of a religious, charitable, educational, or other organization exempt from income tax under section 101 (6), but this subparagraph shall not apply to service performed during the period for which a certificate, filed pursuant to subsection (l), is in effect if such service is performed by an employee (i) whose signature appears on the list filed by such organization under subsection (l), or (ii) who became an employee of such organization after the calendar quarter in which the certificate was filed;

* * * * *

(11) (A) * * *

(B) Service performed in the employ of a school, college, or university if such service is performed, by a student who is enrolled and is regularly attending classes at such school, college, or university;

* * * * *

(14) Service performed as a student nurse in the employ of a hospital or a nurses' training school by an individual who is enrolled and is regularly attending classes in a nurses' training school chartered or approved pursuant to State law; and service performed as an interne in the employ of a hospital by an individual who has completed a four years' course in a medical school chartered or approved pursuant to State law;

* * * * *

(e) Section 1426 of the Internal Revenue Code is amended by * * * inserting * * * the following:

* * * * *

(l) *Exemption of religious, charitable, etc., organizations*—(1) *Waiver of exemption by organization.* An organization exempt from income tax under section 101 (6) may file a certificate (in such form and manner, and with such official, as may be prescribed by regulations made under this subchapter) certifying that it desires to have the insurance system established by title II of the Social Security Act extended to service performed by its employees and that at least two-thirds of its employees concur in the filing of the certificate. Such certificate may be filed only if it is accompanied by a list containing the signature, address, and social security account number (if any) of each employee who concurs in the filing of the certificate. Such list may be amended, at any time prior to the expiration of the first month following the first calendar quarter for which the certificate is in effect, by filing with such official a supplemental list or lists containing the signature, address, and social security account number (if any) of each additional employee who concurs in the filing of the certificate. The list and any supplemental list shall be filed in such form and manner as may be prescribed by regulations made under this subchapter. The certificate shall be in effect (for the purposes of subsection (b) (9) (B) and for the purposes of section 210 (a) (9) (B) of the Social Security Act) for the period beginning with the first day following the close of the calendar quarter in which such certificate is filed, but in no case shall such period begin prior to January 1, 1951. The period for which the certificate is effective may be terminated by the organization, effective at the end of a calendar quarter, upon giving two years' advance notice in writing, but only if, at the time of the receipt of such notice, the certificate has been in effect for a period of not less than eight years. The notice of termination may be revoked by the organization by giving, prior to the close of the calendar quarter specified in the notice of termination, a written notice of such revocation. Notice of termination or revocation thereof shall be filed in such form and manner, and with such official, as may be prescribed by regulations made under this subchapter.

(2) *Termination of waiver period by Commissioner.* If the Commissioner finds that any organization which filed a certificate pursuant to this subsection has failed to comply substantially with the requirements of this subchapter or is no longer able to comply therewith, the Commissioner shall give such organization not less than sixty days' advance notice in writing that the period covered by such certificate will terminate at the end of the calendar quarter specified in such notice. Such notice of termination may be revoked by the Commissioner by giving, prior to the close of the calendar quarter specified in the notice of termination, written notice of such revocation to the organization. No notice of termination or of revocation thereof shall be given under this paragraph to an organization without the prior concurrence of the Federal Security Administrator.

(3) *No renewal of waiver.* In the event the period covered by a certificate filed pursuant to this subsection is terminated by the organization, no certificate may again be filed by such organization pursuant to this subsection.

* * * * *

(g) The amendments made by subsections * * * (e) * * * of this section shall be applicable only with respect to services performed after 1950.

SECTION 205 OF THE SOCIAL SECURITY ACT AMENDMENTS OF 1950

DEFINITION OF EMPLOYEE

(a) Section 1426 (d) of the Internal Revenue Code is amended to read as follows:

(d) *Employee.* The term "employee" means—

(1) Any officer of a corporation; or

(2) Any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee; or

(3) Any individual (other than an individual who is an employee under paragraph (1) or (2) of this subsection) who performs services for remuneration for any person—

(A) As an agent-driver or commission-driver engaged in distributing meat products, vegetable products, fruit products, bakery products, beverages (other than milk), or laundry or dry-cleaning services, for his principal;

(B) As a full-time life insurance salesman;

(C) As a home worker performing work, according to specifications furnished by the person for whom the services are performed, on materials or goods furnished by such person which are required to be returned to such person or a person designated by him, if the performance of such services is subject to licensing requirements under the laws of the State in which such services are performed; or

(D) As a traveling or city salesman, other than as an agent-driver or commission-driver, engaged upon a full-time basis in the solicitation on behalf of, and the transmission to, his principal (except for sideline sales activities on behalf of some other person) of orders from wholesalers, retailers, contractors, or operators of hotels, restaurants, or other similar establishments for merchandise for resale or supplies for use in their business operations;

if the contract of service contemplates that substantially all of such services are to be performed personally by such individual; except that an individual shall not be included in the term "employee" under the provisions of this paragraph if such individual has a substantial investment in facilities used in connection with the performance of such services (other than in facilities for transportation), or if the services are in the nature of a single transaction not part of a continuing relationship with the person for whom the services are performed.

(b) The amendment made by this section shall be applicable only with respect to services performed after 1950.

§ 408.1 *Scope of part.* The regulations in this part relate to the provisions of section 1426 (b) (9) (B) and section 1426 (*l*) of the Federal Insurance Contributions Act, added by section 204 (a) and (e) of the Social Security Act Amendments of 1950, approved August 28, 1950. Such provisions relate to the waiver of exemption from the taxes imposed under the Federal Insurance Contributions Act by an organization which is exempt from income tax under section 101 (6) of the Internal Revenue Code and which desires to have the insurance system established by title II of the Social Security Act extended to services performed by its employees.

§ 408.2 *Who may waive exemption.* (a) Any organization that is exempt from income tax under section 101 (6) of the Internal Revenue Code may waive its exemption from the taxes imposed under the Federal Insurance Contributions Act by filing a certificate on Form SS–15, provided that at least two-thirds of the employees of the organization concur in the filing of the certificate. The organization must be exempt from income tax under section 101 (6) for the taxable year in which the certificate is filed; otherwise, the Form SS–15 filed by the organization is void.

(b) If the period covered by the certificate is terminated by the organization, no certificate may again be filed by the organization under section 1426 (*l*).

§ 408.3 *Form and effect of waiver.* (a) The certificate on Form SS–15 shall be filed with the collector of internal revenue for the district in which is located the principal office or principal place of business of the organization. The organization shall certify in the certificate that it desires to have the insurance system established by title II of the Social Security Act extended to service performed by its employees and that at least two-thirds of its employees, determined on the basis of the facts existing as of the date the certificate is filed, concur in the filing of the certificate.

(b) All individuals who are employees of the organization within the meaning of section 1426 (d) of the Federal Insurance Contributions Act, as amended by section 205 of the Social Security Act Amendments of 1950, shall be included in determining whether two-thirds of the employees of the organization concur in the filing of the certificate; except that there shall not be included (1) those employees who at the time of the filing of the certificate are performing for such organization services only of the character specified in paragraphs (9) (A), (11) (B), and (14) of section 1426 (b) of the Federal Insurance Contributions Act, as amended by section 204 of the Social Security Act Amendments of 1950, and (2) those alien employees who at the time of the filing of the certificate are performing services for such organization under an arrangement which provides for the performance only of services outside the United States not on or in connection with an American vessel or American aircraft. As used in the preceding sentence, the term "alien employee" does not include an employee who is a citizen of Puerto Rico or of the Virgin Islands, and the term "United States" includes Puerto Rico and the Virgin Islands.

(c) The certificate may be filed only if it is accompanied by a list on Form SS–15a, containing the signature, address, and social security account number (if any) of each employee who concurs in the filing of the certificate. The list accompanying the certificate may be amended, at any time prior to the expiration of the first month following the first calendar quarter for which the certificate is in effect, by filing a supplemental list or lists on Form SS–15a Supplement, containing the signature, address, and social security account number (if any) of each additional employee who concurs in the filing of the certificate.

(d) The certificate shall be in effect for the period beginning with the first day following the close of the calendar quarter in which the certificate is filed, but in no case shall the effective period begin prior to January 1, 1951. Thus, if the certificate is filed on or before December 31, 1950, it will be in effect with respect to services performed in the employ of the organization on and after January 1, 1951. For termination of the waiver, see §§ 408.4 and 408.5. The certificate is not terminated if the organization loses its exemption under section 101 (6) of the Internal Revenue Code, but continues effective with respect to any subsequent periods during which the organization is so exempt.

(e) Service performed in the employ of an organization which has duly filed a certificate is not excepted from employment under section 1426 (b) (9) (B) of the Federal Insurance Contributions Act, during the period for which the certificate is in effect, if such service is performed by an employee (1) whose signature appears on the list filed by the organization on Form SS–15a, or on Form SS–15a Supplement, or (2) who becomes an employee of the organization after the calendar quarter in which the certificate is filed. Consequently, the taxes imposed under the Federal Insurance Contributions Act will apply to the organization and to each employee whose services constitute employment and whose signature appears on the accompanying list or on any supplemental list or lists filed within the prescribed time, commencing with the first day following the close of the calendar quarter in which the certificate is filed (but in no event prior to January 1, 1951). Such taxes will also apply immediately with respect to services which constitute employment performed by any individual who enters the employ of the organization on or after the first day following the close of the calendar quarter in which the certificate is filed. The reemployment by the organization of a former employee after the certificate becomes effective shall be considered for the purposes of such taxes as a new employment, regardless of whether or not such individual concurred in the filing of the certificate.

(f) In the case of a certificate filed by an organization in 1950, an individual who performed services for such organization during the calendar quarter in which the certificate was filed and who continued to perform services for such organization in the next calendar quarter shall not be considered to have begun a new employment solely by reason of the change made by section 205 of the Social Security Act Amendments of 1950 in the definition of the term "employee" in section 1426 (d) of the Federal Insurance Contributions Act.

§ 408.4 *Termination of waiver by organization.* (a) The period for which the certificate is in effect may be terminated by the organization upon giving two years' advance notice in writing to the Commissioner of Internal Revenue of the organization's desire to terminate the effect of the certificate at the end of a specified calendar quarter, but only if, at the time of the receipt of such notice by the Commissioner, the certificate has been in effect for a period of not less than eight years.

(b) In computing the effective period which must precede the date of receipt of the notice of termination, there shall be disregarded any period or periods as to which the organization is not exempt from income tax under section 101 (6) of the Internal Revenue Code.

(c) The notice of termination may be revoked by the organization by giving, prior to the close of the calendar quarter specified in the notice of termination, a written notice to the Commissioner of such revocation.

§ 408.5 *Termination of waiver by Commissioner.* (a) The period for which the certificate is in effect may be terminated by the Commissioner of Internal Revenue, with the prior concurrence of the Federal Security Administrator, upon a finding by the Commissioner that the organization has failed to comply substantially with the requirements of the Federal Insurance Contributions Act or is no longer able to comply therewith. The Commissioner shall give the organization not less than sixty days' advance notice in writing that the period covered by the certificate will terminate at the end of the calendar quarter specified in the notice of termination.

(b) The notice of termination may be revoked by the Commissioner, with the prior concurrence of the Federal Security Administrator, by giving written notice of revocation to the organization prior to the close of the calendar quarter specified in the notice of termination.

PAR. 2. Effective January 1, 1951, Regulations 106, as amended (26 CFR, Part 402), relating to the employees' tax and the employers' tax under the Federal Insurance Contributions Act (subchapter A of chapter 9 of the Internal Revenue Code), are modified to the extent such regulations are inconsistent with the regulations promulgated under paragraph 1 of this Treasury decision.

Because of the short period of time remaining in 1950 and because it is contemplated by the Social Security Act Amendments of 1950 that certificates under section 1426 (l) of the Internal Revenue Code may be filed in 1950 so as to be in effect commencing January 1, 1951, it is found that it is impracticable and unnecessary to issue this Treasury

decision subject to the effective date limitation of section 4 (c) of the Administrative Procedure Act, approved June 11, 1946.

[SEAL] GEO. J. SCHOENEMAN,
Commissioner of Internal Revenue.

Approved: December 27, 1950.

THOMAS J. LYNCH,
Acting Secretary of the Treasury.

[F. R. Doc. 50-12591; Filed, Dec. 29, 1950; 8:51 a. m.]

TITLE 32—NATIONAL DEFENSE

Chapter IV—Joint Regulations of the Armed Forces

Subchapter D—Military Renegotiation Regulations

[Amdt. 11]

PART 421—AUTHORITY AND ORGANIZATION FOR RENEGOTIATION

PART 425—AGREEMENTS, CLEARANCES AND STATEMENTS

PART 427—MILITARY RENEGOTIATION FORMS

PART 428—STATUTES, ORDERS AND DIRECTIVES

MISCELLANEOUS AMENDMENTS AND CORRECTIONS

The following corrections and amendments are made to this subchapter:

1. Part 421 is amended in the following respects: § 421.110 is amended as follows: Delete the words, "the Circuit Court of Appeals or", and the words, "for the District of Columbia", and insert an "s" to the word "Court" to read "United States Courts of Appeals."

2. Part 425 is amended in the following respects: § 425.502 is amended as follows: Delete therefrom the word, "standard".

(Sec. 3, 62 Stat. 259; 50 U. S. C. App. Sup., 1193)

3. Part 427 is amended in the following respects:

a. Section 427.701 is amended as follows: In the last sentence of the last paragraph of the text of the letter incorporated in this section, delete the words, "at a price of $2.50."

b. Section 427.702–1 is amended as follows: Under the heading "General Comments", delete the second paragraph and substitute therefor the following: "The Military Renegotiation Regulations, including all amendments and supplements thereto, printed on sheets punched for a standard loose leaf binder, may be purchased from the Superintendent of Documents, Washington 25, D. C., by subscription only. The Military Renegotiation Policy and Review Board cannot honor requests for this item."

c. Section 427.704 is amended as follows: In the paragraph preceding the heading "Section A. Financial Statements", delete the second and third sentences thereof and insert the following: "Subscriptions for the Military Renegotiation Regulations and Amendments thereto should be addressed to the Superintendent of Documents, Washington 25, D. C."

d. 427.741–3 is amended as follows: Delete the word "standard" between the words "the" and "form" in the first paragraph thereof.

(Sec. 3, 62 Stat. 259; 50 U. S. C. App. Sup., 1193)

4. Part 428 is amended in the following respects:

a. Section 428.841 is amended to be the general heading and to read as follows: "§ 428.841 *Raw materials exemption.*"

b. Following the general heading, namely, "§ 428.841 *Raw materials exemption.*", delete the first paragraph before the parenthetical note, "(NOTE: This list may be modified from time to time.)", and in lieu thereof substitute and insert the following new section before the said parenthetical note:

§ 428.841–1 *List of exempt products.* Subject to the provisions of § 428.841–2, the Military Renegotiation Policy and Review Board has determined that contracts and subcontracts for any of the products on the following list are exempt from renegotiation pursuant to the provisions of subsection (i) (1) (B) of the Renegotiation Act of February 25, 1944, as amended, adopted by reference by section (d) of the 1948 Act. See § 423.343–1.

c. Section 428.841–1 is amended by adding to the "List of Exempt Products", at the end thereof, the following new item:

Zinc ores and concentrates; zinc anodes, bars, oxide, and slabs.

(Sec. 3, 62 Stat. 259; 50 U. S. C. App. Sup., 1193)

d. The following new section is added to read as follows:

§ 428.841–2 *Limitation.* (a) Subject to the provisions of § 428.841–2 (b), it is determined that each of the products listed in § 428.841–1 is "the product of a mine, oil or gas well, or other mineral or natural deposit, or timber, which has not been processed, refined, or treated beyond the first form or state suitable for industrial use," within subsection (i) (1) (B) of the Renegotiation Act of February 25, 1944, as amended, adopted by reference by subsection (d) of the 1948 Act.

(b) This determination is made under the principles set forth in § 423.343–1 of this subchapter. The products listed in § 428.841–1 are exempt only when they represent products of a mine, oil or gas well, or other mineral or natural deposit, or timber, which have not been processed, refined or treated beyond the first form or state suitable for industrial use and are not exempt if manufactured from raw materials which do not fall within the above description or which have at some prior stage been processed, refined or treated beyond such first form or state suitable for industrial use. For example, secondary aluminum pigs and ingots are not considered exempted products.

Adopted by the Board: December 7 and 14, 1950.

(Sec. 3, 62 Stat. 259; 50 U. S. C. App. Sup., 1193. Interprets or applies sec. 508, 56 Stat. 964, as amended, sec. 1, 56 Stat. 1013, sec. 401, 62 Stat. 1049; 26 U. S. C. 3806, 35 U. S. C. 89, 50 U. S. C. App. Sup., 1193 note)

FRANK L. ROBERTS,
Chairman, Military Renegotiation Policy and Review Board.

[F. R. Doc. 50-12388; Filed, Dec 29, 1950; 9:00 a. m.]

[Appendix A to Subpart E of Part 423, Amdt. 6]

PART 423—DETERMINATION OF RENEGOTIABLE BUSINESS AND COST

GENERAL CLASSES OR TYPES OF EXEMPTED CONTRACTS AND SUBCONTRACTS

Section 423.354, Appendix A (15 F. R. 6473) hereby is amended, as follows:

1. Item 6 thereof relating to "Collateral Items" is amended by deleting the figure "6" and inserting in lieu thereof the following, "6–1", and adding after and following the heading, *"Collateral Items,"* a parenthetical note, as follows: "(With respect to the period May 21, 1948, through December 31, 1950)."

2. By adding a new item, designated as "6–2", to read, as follows:

6–2. *Collateral items.* (With respect to the period January 1, 1951, through June 30, 1951.)

(a) *Exemption.* All subcontracts for:

(1) The sale, furnishing, or installation, of machinery used in the processing of other machinery to be used in the processing of an end product or of an article incorporated therein.

(2) The sale, furnishing, or installation of component parts of, or subassemblies for, machinery included in (1) above.

(3) The performance of services directly required for the performance of subcontracts included in (1) and (2) above.

As used herein the phrase "used in processing" has the same meaning as set forth in § 423.333 of the Military Renegotiation Regulations.

(b) *Limitations on Exemption.* The termination date of this exemption is June 30, 1951.

This exemption does not apply to subcontracts where the purchaser of such machinery has acquired it for the account of the Government. As used herein the phrase "acquired it for the account of the Government" means acquired pursuant to an arrangement between the Government and the purchaser of such machinery, whereby title to such machinery will, or may, at the option of the Government, vest in the Government.

(c) *Comment.* The scope of the collateral items exemption as it applied prior to January 1, 1951, excluded from renegotiation all subcontracts for items which did not become a part of the end product or of a component incorporated therein. This exemption excludes from renegotiation a narrower group of subcontracts. The termination of the exemption which applied prior to January 1, 1951, has the effect of bringing back within the scope of renegotiation all subcontracts for items of machinery, equipment, and materials which operate directly on an end product or of an article incorporated therein by chemical, physical, or mechanical methods, such as shaping, cutting, constructing, combining, refining, assembling, testing, or inspecting. Furthermore, all subcontracts for components of such machinery, equipment, or materials

will likewise be subject to renegotiation. For example, if an aircraft manufacturer buys a machine on or after January 1, 1951, for use in performing a renegotiable contract, the purchase of that machine will be a subcontract subject to renegotiation. Furthermore, purchases made by the manufacturer of the machine of components to be incorporated therein will likewise be subject to renegotiation if such purchases are made on or after January 1, 1951.

Adopted by the Board: December 19, 1950.

(Sec. 3, 62 Stat. 259; 50 U. S. C. App. Sup. 1193)

FRANK L. ROBERTS,
Chairman, Military Renegotiation Policy and Review Board.

[F. R. Doc. 50-12389; Filed, Dec. 29, 1950; 9:00 a. m.]

Chapter XVI—Selective Service System

[Amdt. 15]

PART 1621—PREPARATION FOR CLASSIFICATION

PREPARING LIST OF REGISTRANTS

The Selective Service Regulations are hereby amended as follows:

Paragraph (a) of § 1621.5 is amended to read as follows:

§ 1621.5 *Preparation of list of registrants (SSS Form No. 3).* (a) When the local board has completed the numbering of the Registration Cards (SSS Form No. 1) as prescribed in paragraph (c) of § 1621.4 the List of Registrants (SSS Form No. 3) shall be prepared in duplicate and will be a permanent roster of all registrants of the local board. A separate List of Registrants (SSS Form No. 3) shall be prepared by the local board for each group of registrants who were born in any one year. On each List of Registrants (SSS Form No. 3) shall be entered the names of the registrants, their dates of birth, their places of residence, and their selective service numbers. Registrants shall be listed on the List of Registrants (SSS Form No. 3) in the order of their dates of birth commencing with the oldest registrant except that the names of late registrants and of registrants whose Registration Cards (SSS Form No. 1) are received late shall be placed at the bottom of the list for registrants of their year of birth.

(Sec. 10, 62 Stat. 618; 50 U. S. C. App., Sup., 460; E. O. 9979, July 20, 1948, 13 F. R. 4177; 3 CFR, 1948 Sup.)

The foregoing amendment to the Selective Service Regulations shall be effective immediately upon the filing hereof with the Division of the Federal Register.

LEWIS B. HERSHEY,
Director of Selective Service.

DECEMBER 28, 1950.

[F. R. Doc. 50-12385; Filed, Dec. 28, 1950; 4:50 p. m.]

TITLE 32A—NATIONAL DEFENSE, APPENDIX

Chapter I—National Production Authority, Department of Commerce

[NPA Notice]

PART 9—DESIGNATION OF SCARCE MATERIALS

EDITORIAL NOTE: NPA Notice 1 (F. R. Doc. 50-12584), published at page 9398 of the issue for Friday, December 29, 1950, is hereby designated Part 9 of Title 32A, Chapter I, as set forth above, and the text of List A is designated "§ 9.1 *List A—Designation of scarce materials.*"

TITLE 39—POSTAL SERVICE

Chapter I—Post Office Department

PART 92—TRANSPORTATION OF MAILS BY RAILROADS

COMPREHENSIVE PLAN OF POSTMASTER GENERAL

WHEREAS a revised Comprehensive Plan of the Postmaster General for the transportation of United States Mail by Railroad, effective January 1, 1951, and rules and regulations of the Postmaster General implementing service requirements of the revised Comprehensive Plan, also effective January 1, 1951, have been filed with the Interstate Commerce Commission and served on Railroad Companies engaged in the transportation of the United States Mails, in connection with the Railway Mail Pay case before the Interstate Commerce Commission (I. C. C. Docket No. 9200), and, in view of the foregoing, it having been found that compliance with the notice, public rule making procedure, and effective date requirements of the Administrative Procedure Act (5 U. S. C. 1003) is unnecessary,

Now, therefore, it is ordered, That, effective January 1, 1951, Part 92 of Title 39, Code of Federal Regulations (39 CFR Part 92; 15 F. R. 3485), be amended as follows:

1. In the text of Part 92, strike out all matter following "RAILWAY MAIL PAY" (§§ 92.52 to 92.61, inclusive), and insert, in lieu thereof, the following:

COMPREHENSIVE PLAN OF THE POSTMASTER GENERAL FOR THE TRANSPORTATION OF UNITED STATES MAIL BY RAILROAD

RULES OF THE POSTMASTER GENERAL IMPLEMENTING SERVICE REQUIREMENTS OF THE COMPREHENSIVE PLAN FOR THE TRANSPORTATION OF UNITED STATES MAIL BY RAILROAD

AUTHORITY: §§ 92.52 to 92.83 issued under R. S. 161, 396, 39 Stat. 419, 425-431, secs. 304, 309, 42 Stat. 24, 25; 5 U. S. C. 22, 369, 39 U. S. C. 523-541, 542-568.

COMPREHENSIVE PLAN OF THE POSTMASTER GENERAL FOR THE TRANSPORTATION OF UNITED STATES MAIL BY RAILROAD

§ 92.52 *Transportation of the mail.* (a) All railway common carriers engaged in the transportation of United States mail shall transport such mail in the manner, under the conditions, and with the service prescribed by the Post Office Department, and otherwise in accordance with the provisions of the Railway Mail Pay Act of 1916.

(b) Any railway common carrier desiring to be relieved of the transportation of the mail may make application to the Post Office Department accordingly, and consideration will be given to the granting of its request in whole or in part as the needs of the Postal Service will permit.

(c) Mail shall be carried upon such trains as the Post Office Department shall designate from time to time in the interest of the Postal Service, and the character of trains carrying the mails shall be that of the passenger train operating between passenger or mail handling facilities. When required by the interests of the Postal Service, the Department may provide for the movement of mail between passenger or special mail handling facilities in other than passenger trains.

(d) The transit time of trains upon which mail is transported shall be that which is maintained by the carriers for their general transportation business in connection with their published schedules.

(e) Each railway common carrier engaged in the transportation of mail is required to furnish such cars as are necessary for the service authorized by the Post Office Department.

§ 92.53 *Classes and nature of service.* (a) The service shall be of the following classes:

(1) *Full railway post office car service.* Service of this class shall be authorized in standard cars, 60 feet in length, inside measurement, constructed and fitted in accordance with the plans and specifications approved by the Post Office Department for the handling, distribution, storage, and delivery of mail by postal transportation clerks. The requirements for service in such cars shall include the sanitation, cleaning, heating, lighting, and the furnishing of ice and drinking water, both in terminals and en route. When required, such cars shall be suitably placed and made available for advance distribution before train departure.

(2) *Railway post office apartment car service.* Service of this class shall be authorized in standard apartments, 30 and 15 feet in length, inside measurement. The apartment shall be separated from the remainder of the car by a partition. The requirements for service are essentially the same as in full railway post office cars with respect to construction and furnishings, sanitation, cleaning, heating, lighting, furnishing of ice and drinking water, and the placing of apartment cars for advance distribution.

(3) *Storage car service.* Service of this class shall be authorized in standard cars, 60 feet in length, inside measurement, except as hereinafter provided, used exclusively for mails. This service is the transportation and handling of made-up mails in bulk and the requirements for this service shall include the maintenance and cleaning of the cars. The handling of mail into and from all storage cars shall be performed by employees of the railroad companies under instructions of postal employees with respect to proper routing and separation of mails.

(4) *Lesser storage unit service.* Service of this class shall be authorized in less than full-car units of space in mixed traffic, combination, or other cars. This service shall be the transportation and handling of mails of the same type as those handled in storage cars. The requirements for lesser storage unit service are the same as for service in storage cars.

(b) *Nature of services.* The services which the railroads are to render in connection with mail transportation shall be as follows:

(1) Railroad companies are required to perform all necessary switching of cars; to load all mail into cars so as to obtain maximum utilization of the space authorized, including the proper separation, piling, and storing of such mail; and to unload mail from all cars. Handling of all mail within railway post office cars and apartments shall be performed by postal transportation clerks.

(2) Railroad companies are required to transfer all mails between cars in the same train where such transfers are necessary and required by the Post Office Department.

(3) Railroad companies are required to take mails in transit from and deliver them to Government employees and contractors at an accessible point at railroad stations for transfer to and from post offices or railroad stations, and to transfer mails between trains operating into and out of the same railroad station, as required by the Post Office Department.

(4) Railroad companies are required to furnish all necessary facilities for caring for and handling mails, including suitable and adequate space and rooms in their stations for storing and transfer of mails in transit. They shall also furnish suitable and adequate office space for transfer clerks of the Postal Transportation Service when required by the Post Office Department.

(5) Railroad companies are required to transport without extra charge the persons in charge of the mails and the agents and officers of the Post Office Department and Postal Transportation Service, under the conditions prescribed by law and regulations pursuant thereto.

(6) Railroad companies are required to construct, light, and maintain mail cranes and other adequate facilities for the exchange of mails at points or stations on the run where the train does not stop and exchange of mails is necessary.

(7) Railroad companies are required to take the mails from their railroad terminals and stations and deliver them into post offices, postal stations, and Postal Transportation Service terminals; take the mails from post offices, postal stations, and Postal Transportation Service terminals, and deliver them into their railroad terminals and stations; and take the mails from their stations and deliver them into other railroad stations where the distance does not exceed 80 rods, unless other provision for this service is made by the Post Office Department.

§ 92.54 *Authorizations.*—(a) *General.* (1) The anticipated space needs of the Department shall be reflected by regular authorizations which shall be restricted to the needs of the service between established railway passenger or freight division points or junctions. Regular authorizations shall be determined in accordance with such instructions as may be issued by the Postmaster General. Regular authorizations for railway post office cars and railway post office apartments shall remain in effect unless and until modified as herein provided. Regular authorization for other classes of service shall be effective for a period of one calendar month, subject to modification or cancellation of service as provided herein.

(2) Excess service may be requested of railroad companies in trains in which no unit of space is regularly authorized or in trains in which the regularly authorized space is inadequate to accommodate the mails available for dispatch. Requests for excess service shall be restricted to the needs of the Service and shall be made in accordance with the instructions issued by the Postmaster General.

(3) Railroad companies are required to anticipate the needs for service only to the extent of the regular space authorizations. Where there are excess mails and baggage or express or both to be loaded, and the available space is not sufficient to accommodate all, the mails must be given preference. Railroad companies will not, however, be required to unload baggage or express in order to provide space for the excess mail.

(4) The class, frequency, and distance of service to be authorized shall be determined in accordance with the needs of the Postal Service and under such rules and regulations or instructions as shall be prescribed by the Postmaster General.

(b) *Equipment.* (1) Authorization for railway post office cars shall be for cars of the standard length of 60 feet. Authorizations for railway post office apartments shall be for the standard lengths of 30 or 15 feet, as the needs of the Postal Service require. If a railroad company is unable to furnish standard railway post office cars and apartment cars, the Department may accept nonstandard railway post office equipment as a convenience to the carriers provided compensation not exceeding pro rata pay is accepted for the facilities furnished. Any deficiency may be provided in another car in the train when necessary and in such case full pay will be made for the standard car authorized.

(2) The Department does not require and will not authorize railway post office equipment longer than the standard lengths specified herein. However, as a convenience to the carriers, and to enable them to obtain revenue from the operation of space which otherwise might be unused, the Department will accept the excess space beyond the standard lengths authorized for the accommodation of lesser storage unit service when needed.

(3) Cars in excess of 60 feet in which a railway post office unit of 60 feet is partitioned from the remainder of the car may be accepted to fulfill an authorization for a railway post office car of 60 feet.

(4) When a railroad company is unable to furnish cars of the standard length authorized for storage car service, the Department may accept cars less than 60 feet in length, inside measurement, provided compensation not exceeding pro rata pay is accepted for the length of the car furnished. The Department may accept storage cars of greater length than the standard, provided compensation not exceeding pro rata pay is accepted in accordance with rules and regulations of the Postmaster General.

(c) *Modification of authorizations.* (1) Authorizations for full railway post office car service and railway post office apartment service shall be subject to modification at any time to provide for new and additional service, discontinuance of service, or reduction in service.

(2) Regular authorizations for storage car service and lesser storage unit service shall not be discontinued or reduced during the calendar month unless discontinuance or reduction in the serv-

ice is necessitated by service changes. Regular authorization for storage car service and lesser storage unit service shall be subject to modification at any time to provide for new and additional service.

(3) Requests for excess service may be made at any time during the calendar month.

(d) *Cancellations.* (1) Whenever there is insufficient mail on any day to warrant the operation of a full storage car, the regular authorization may be cancelled by a representative of the Post Office Department at the initial point of the run of the car. Reasonable advance notice of such cancellation shall be given to the railroad company at the initial point of the run of the car to permit the car to be removed from the train.

(2) Authorizations for classes of service other than full storage car service shall not be cancelled during the calendar month.

RULES OF THE POSTMASTER GENERAL IMPLEMENTING SERVICE REQUIREMENTS OF THE COMPREHENSIVE PLAN FOR THE TRANSPORTATION OF UNITED STATES MAIL BY RAILROAD

§ 92.55 *Non-standard railway post-office cars and apartments.* (a) Where the railroad company is unable to furnish a standard full or apartment railway post-office car, the operation in lieu thereof of a non-standard car which does not provide as much storage space as a standard car may be permitted, provided that pro rata pay is accepted for the non-standard car based on the storage space furnished as compared with the storage space due in a standard car of the unit authorized. Full payment will be made, however, when the entire deficiency in storage space is made up, when necessary, in another part of the train.

(b) The operation of a smaller railway post-office car than the unit authorized which provides sufficient distribution facilities for the particular run of the car may be permitted provided that pro rata pay is accepted based on the length of the car furnished as compared with the length of the unit authorized. If such car is deficient in storage space as compared with a standard car, full payment may be made on the basis of the length of the full or apartment railway post-office car furnished, provided the entire deficiency in storage space is made up, when necessary, in another part of the train.

(c) Where there is a deficiency of distributing facilities in the railway post-office car, the company will be required to install at least such additional facilities as are needed on the particular run of the car or cars involved.

NOTE: The storage-space requirements in linear feet in full and apartment railway post-office cars, based on the standard plans dated April 1, 1949, are as follows: 60-foot full cars, 11 feet 10 inches; 30-foot apartment cars, 4 feet 9 inches; and 15-foot apartment cars, 3 feet 2 inches.

(d) A passageway or part-width apartment railway post-office car may be operated to fill an authorization for a standard apartment railway post-office car, provided that the number of square feet of floor space furnished is equal to or greater than the number of square feet provided in a standard apartment railway post-office car of the size authorized, and provided that pro rata pay on the basis of the square feet of floor space is accepted where the floor space is less than that in a standard car. If such car is deficient in storage space as compared with a standard car, full payment may be made on the basis of the number of square feet of floor space furnished, provided the entire deficiency in storage space is made up, when necessary, in another part of the train.

(e) Apartment railway post-office cars on narrow-gauge lines will be regarded the same as standard-width cars. The amount of storage space required in narrow-gauge apartment railway post-office cars is the amount provided by the standard plan of a narrow-gauge car and not the amount provided by the plan for a standard-gauge apartment car.

§ 92.56 *Nonstandard storage cars.* (a) Where 60- or 70-foot storage cars are authorized and the railroad company is unable to furnish cars of such length, but furnishes cars of lesser length than authorized, the Post Office Department may accept such cars provided pro rata compensation is accepted based on the length of the car furnished and used.

(b) Where a 70 foot car is authorized, the Department may accept a car of greater length provided compensation for a 70 foot car is accepted where the volume of mail does not exceed 70 feet, and where the volume of mail exceeds 70 feet, provided pro rata compensation is accepted for the volume of mail carried in the car.

(c) Where a 60 foot car is authorized, the Department may accept a car of greater length provided compensation for a 60 foot car is accepted where the volume of mail does not exceed 60 feet and, where the volume of mail exceeds 60 feet, provided compensation is accepted in the same manner as if a 70 foot car had been authorized.

§ 92.57 *Authorization of excess service.* (a) Excess service shall be authorized under special request by a representative of the Postal Transportation Service, or under the initiative action of railroad employees at points where no representative of the Postal Transportation Service is located.

(b) Where there is no other available space in the train except that in an oversize railway post-office car, the mails shall be accommodated in such space.

(c) Where excess mails are carried in two or more cars in a train, a single request form shall be issued for a unit of sufficient size to cover the entire excess mails carried. This is not to be considered as affecting the provisions of § 92.60, which provides for the authorization of a 60- or 70-foot storage car in lieu of a lesser storage unit under certain conditions.

§ 92.58 *Mails not to be carried on trains on which no space is authorized except upon request.* (a) The railroad company shall not carry mails on a train upon which no space is regularly authorized unless it receives a request for necessary excess space in such train from the proper representative of the Postal Transportation Service.

(b) Where conditions warrant, a postmaster may be authorized by a general or district superintendent, Postal Transportation Service, to issue requests on proper forms for excess service on unauthorized trains, the railroad company to be advised of the issuance of such authority.

§ 92.59 *Additional space in trains.* (a) When a railway post-office car or a railway post-office car with an additional unit of storage space is regularly authorized in a train and the authorized space is inadequate to accommodate all of the mails offered for dispatch by a particular trip, the transfer clerk or the postal transportation clerk in charge, at point where excess mails are received shall address a written notice, showing the number of bags of mail involved, to the railroad company, requesting it to furnish the additional unit of space needed in the train. Such notice will be made in duplicate, the original to be delivered to the conductor or baggageman of the train and the duplicate to be forwarded to the district superintendent, Postal Transportation Service.

(b) When the regularly authorized space in a train in which there is no railway post-office service, is inadequate to accommodate all of the mails offered for dispatch by a particular trip, the transfer clerk or other postal representative at the point where the excess mails develop shall address a written notice, showing the volume of mail involved, to the railroad company requesting it to furnish the additional unit of space needed in the train, such notice to be made in duplicate, the original to be delivered to the designated representative of the railroad company and the duplicate to be forwarded to the district superintendent, Postal Transportation Service.

(c) At points where no representative of the Postal Service is located and the regularly authorized space in the train is inadequate to accommodate all of the mails offered for dispatch by a particular trip, the baggagemen on the train shall accept and count all mail offered and the railroad company shall advise the district superintendent, Postal Transportation Service, as to the number of bags of excess mail and the points between which they were carried, and, if from a missed connection, whether such mails were from the train of the same company.

§ 92.60 *Storage car in lieu of.* (a) Where a regularly authorized unit of storage space, combined with an excess unit necessitates the use of more than 30 feet of linear space in a baggage car, or storage car, used exclusively for the mails, a 60-foot car shall be authorized from the point where more than 30 feet of linear space is needed to the first established railway passenger or freight division point, or junction where the 60-foot car may be reduced or discontinued. The 60-foot cars authorized under this section shall be included in the pay claim for regularly authorized service and appear in such pay claim immediately fol-

lowing the item of regular service affected.

(b) Where a regularly authorized 60-foot storage car or lesser storage unit, combined with an excess unit necessitates the use of more than 60 feet of linear space in a baggage car or storage car, used exclusively for the mails, a 70-foot car shall be authorized from the point where more than 60 feet of linear space is needed to the first established railway passenger or freight division point or junction where the 70-foot car may be reduced or discontinued. The 70-foot car authorized under this rule shall be included in the report of regularly authorized service and appear in such report immediately following the item of regular service affected.

§ 92.61 *Handling, loading, and unloading of storage mail.* (a) Storage cars should be loaded solid at the initial point of the run, as far as practicable, without aisle or vacant space in the doorways, excepting such doorways and aisles as may be needed en route for the handling of mail.

(b) Where a unit of storage space is carried in an oversize railway post-office car, the mails carried in such unit shall be handled by postal transportation clerks to and from the doorways of the car.

(c) Where a storage car is operated next to a full RPO or apartment RPO car, or where mail is carried in the baggage end of RPO cars, and postal transportation clerks have access thereto through end doors, the handling of mails at intermediate points where the volume is small may be performed by the clerks when considered advisable by the Post Office Department.

(d) Railroad companies may be required to transfer all or a part of the excess mails carried in the baggage car to available space in the authorized distributing or storage unit, at points where such transfer is practicable, upon presentation of request for such transfer on Form 5050 by a representative of the Department. However, if the company desires to carry such mails through to destination in the baggage car in lieu of making the actual transfer, it may do so with the understanding that the space in the baggage car occupied thereby will be charged against the available space in the authorized distributing or storage unit. The request form shall show the point at which the transfer is to be made and the number of bags to be transferred and shall be delivered to the railroad representative immediately upon arrival at the station where the transfer is ordered. Postal transportation clerks will not be required to accept the transfer of such mails through end doors when train is in motion, but they may do so during the station stop if the storage end of the distributing car is next to the baggage car.

§ 92.62 *Railroad companies not required to cut out apartment cars.* Railroad companies will not be required to cut out apartment cars at intermediate points on the authorized run of the car to permit another car which is to be used for advance distribution of the mails to be substituted therefor.

§ 92.63 *Mail carried in several cars of train for convenience of company.* Where mails are carried in several cars in a train out of the initial terminal for the convenience of the company and at some point on the train run the cars are diverged to different lines, or set out at some point, a unit of space of sufficient size to accommodate all of the mails transported in the several cars shall be authorized from the initial point to the point of divergence, or where the car may be set out, except where the volume of mail exceeds the capacity of a storage car, a storage car and an appropriate lesser unit shall be authorized.

§ 92.64 *Mails delivered by fast train to be forwarded or returned to local point on local train, or vice versa, and mails dispatched on train not due to receive them.* Where mails are delivered by a fast train at a certain point from which they are to be forwarded or returned to a local point on a local train, or vice versa, a unit of space will be authorized in the local train for the accommodation of the mails dispatched thereon. However, when for its own convenience the company desires to forward mails on a train not due to receive them from one station to another station for dispatch from such station, permission may be granted for such handling, with the understanding that the space necessary for the accommodation of such mails between the two stations will be furnished without additional compensation and that no delay to the mails will result.

§ 92.65 *Distance of authorization.* (a) Full railway post-office cars and apartment railway post-office cars shall be authorized in both directions and shall be the maximum distribution space needed in either direction of the round-trip car run between established railway passenger or freight division points or junctions at which the trains are scheduled to stop.

(b) Storage cars shall be authorized in one direction only between established railway passenger or freight division points, or junctions, at which the trains are scheduled to stop.

(c) The car run of railway post-office and apartment railway post-office cars and storage cars shall be the movement of a particular unit between established passenger or freight division points or junctions covered by the authorization.

(d) Lesser units of storage space shall be authorized in one direction only. Regular authorizations of lesser units shall not be changed en route at other than established railway passenger or freight division points, or junctions, but they may begin at the point where storage space becomes necessary and may be terminated at the point where the last mails are dispatched. Where necessary space for lesser storage units begins at different points between the same established railway passenger or freight division points, or junctions, on different days of the week, the authorization shall begin at the first point mails are received and shall terminate at the farthest point to which mails are carried on any day of the week.

§ 92.66 *Reports of service performed (pay claims).* Claims must be prepared in such form and manner as prescribed by the Post Office Department.

§ 92.67 *Mails not to be carried until ordered by Department.* Mails shall not be carried on any new railroad, or other railroad or part thereof on which mail service has not been authorized, either regularly or under waivers, until ordered by the Post Office Department.

§ 92.68 *Transfer of mail in emergency.* (a) Whenever a railroad company finds it necessary to transfer at the place of a wreck or washout, its officials and employees shall see that the mails and postal transportation clerks are promptly transferred and every possible convenience furnished the clerks for working their mails.

(b) Whenever a railroad company finds it necessary to set out a car containing mail on account of bad order, or other operating conditions, its employees shall see that all mails in the car are transferred to vacant space in other cars in the train, or to an additional car if available: *Provided*, That where the train involved is an important passenger train and the transfer of all of the mails would result in a protracted delay to the train, the transfer may be limited to first-class and registered mails, daily newspapers, and special delivery, and special handling matter, and also to such other classes of mail as can be handled during the time of such transfer: *Provided further*, That where a following train will secure substantially the same connections and deliveries as would have been made by the train from which the car was set out, the mails may be held for such following train. Where the car set out is a distributing unit, the postal transportation clerks will render all possible assistance in the transfer of the mails.

§ 92.69 *Maintenance of transfer offices by railroads.* Offices at stations for the employees of the Postal Transportation Service engaged in station work shall be lighted, heated, furnished, supplied with ice water, provided with toilet facilities (where such facilities are not easily accessible), and kept in order by the railroad company.

§ 92.70 *Railroads to furnish timetables.* (a) Railroad companies shall forward timetables, not less than 72 hours before taking effect, to the general and district superintendents of the Postal Transportation Service having supervision over the mail service on their lines. If for any reason it becomes necessary to temporarily annul, curtail, or suspend train service, immediate telegraphic notice thereof shall be given the same officials.

(b) At places where railroad companies have agents, such agents shall notify the postmasters as soon as possible after receipt of any notice of change in schedule of mail trains.

§ 92.71 *Advance deliveries by railroads.* When it is desirable to have mails taken from the post office, postal station, or postal transportation terminal to a train, at a point where the service de-

volves upon the company, in advance of the regular closing of the mails, the company shall be required to make such advance delivery as becomes necessary by the requirements of the service.

§ 92.72 *Receipt and dispatch of mail late at night.* (a) Whenever mails are due to be dispatched or are received during the night the railroad company shall, if a representative is on duty, retain custody thereof by placing the mail in a secure and safe room or apartment of the depot or station until it can be given dispatch to the proper train or until the following morning when it shall be delivered at the post office where it is directly contiguous, or to the mail messenger, star route contractor, highway post office clerk, or other contractor, at as early an hour as the necessities of the service may require. The Department reserves the right, however, to require such service of the railroad company at times when the regular representative may not be on duty.

(b) At points where there is no railroad representative employed or on duty and there is a railroad station or depot, the railroad company shall, if deemed necessary by the Postal Transportation Service, provide exchange of mails through use of a safe room in the depot or by means of a safe and suitable locked box at the station.

§ 92.73 *Loading of mails.* (a) Where mail cars are not placed at points accessible to the vehicle of mail messengers or other carriers, the railroad company shall be required to receive the mails from and deliver them to the messenger or other carriers at points accessible to their vehicles, except as provided in § 92.79 (a).

(b) Railroad companies shall furnish the help necessary to handle the mails, to load them into and receive them from the doors of railway post-office cars, and to load and pile the mails in and unload them from storage and baggage cars, except as provided in §§ 92.61 (c) and 92.79 (a). Mails intended for delivery to a postal transportation clerk shall never be placed in a railway post-office car unless there is a clerk on duty to receive and care for them.

§ 92.74 *Holding of trains for loading of mail.* (a) A train shall not depart from a station and leave mails which are being loaded, or are being trucked from vehicles or some part of the station to the train, or are aboard a connecting train that has come to a stop in the same station: *Provided*, That where holding an important train for mails from a delayed connection would cause serious delay and there is subsequent available train service within a reasonable length of time, the Department may authorize a time limit beyond which such train may not be held excepting to load first-class mail, daily newspapers, and foreign mail if necessary to insure steamer connection. If the application of this provision to any train is desired by a railroad company, a request therefor should be made to the general superintendent of the Postal Transportation Service, specifying the reasons and the length of time beyond which it is thought impracticable to hold the train in question. Where such requests are approved by the general superintendent of the Postal Transportation Service, any delayed mail involved under such authority shall be carried on the subsequent train to the extent of any unused space thereon, in lieu of service authorized on the first train. Such requests shall be made with the understanding that no additional pay will be claimed by the company unless the quantity of mail carried in both trains is in excess of that which could have been carried in the space authorized.

(b) Mail trains shall not be held beyond their scheduled time of departure for mail originating in local post offices, Postal Transportation Service terminals, or offices of publication. The Postal Transportation Service shall fix and enforce an ample time limit in which mails shall be delivered to the railroad companies for dispatch.

(c) At joint stations where mails are due to be transferred from a train of one railroad company to a train of another, the mail after being unloaded from the incoming train shall be held to be in the custody of the company operating the train to which the mail is due to be dispatched, and the responsibility for the transfer shall then rest with that company.

(d) Whenever necessary to transfer passengers, baggage, or express from one train to another, for any reason, all mails shall be included in the transfer unless such transfer is a regular connection coming within the provisions of paragraph (a) of this section.

(e) General Superintendents of the Postal Transportation Service may cause to be withheld catalog, circular, parcel post, and ordinary paper mails, in the order named, from dispatch to important trains if necessary and advisable to prevent delay to such trains and forward such mails in other trains in regular or excess space.

§ 92.75 *Exchange of mails at nonstop points.* (a) At all points at which trains do not stop where the Post Office Department deems the exchange of mails necessary, a device for the receipt and delivery of mails satisfactory to the Deparement shall be erected and maintained by the railroad company; and pending the erection of such device the speed of trains shall be slackened so as to permit the exchange to be made with safety.

(b) When mails are caught at night from a crane, the railroad company shall furnish the lantern or light to be attached to the crane and keep it in proper condition, regularly placed, and lighted; also the light shall be so kept and displayed for the guidance of the clerks when delivery only is made. However, if the company has no agent or other employee at the station, the company shall furnish the light, which shall be cared for and placed by the Department's carrier.

(c) The engineer or motorman of a train in which railway post-office service is operated shall give timely notice, by whistle or other signal, of its approach to a nonstop point at which mails are delivered or are taken from a mail crane, or both.

(d) Where the Department deems it necessary to the safe exchange of the mails, the railroad company shall be required to reduce the speed or stop the train.

(e) All railroad companies carrying the mails, unless relieved by the Post Office Department, shall designate one scheduled train in each direction in every twenty-four hours, which will stop at any station or point serving a post office, either regularly or on signal by the postmaster or mail messenger, or notice to the conductor by the postal transportation clerk or baggageman, when deemed necessary for dispatch or receipt of mails. For their convenience, railroad companies may be permitted to handle the mails over the highways by motor vehicle in lieu of the local rail service, under conditions approved by the Post Office Department.

§ 92.76 *Notice of discontinuance of agency or station.* The railroad company shall give 30 days' advance notice to the Post Office Department of the discontinuance of an agency or station, and the company shall not be relieved of the duty of handling the mails at that station unless approved by the Post Office Department.

§ 92.77 *Railroad employees handling mails regarded as agents of railroads.* At places where railroad companies are required to take the mails from and deliver them into post offices or postal stations or to transfer them to connecting railroads, the persons employed to perform such service shall be regarded as agents of the companies and not employees of the postal service, and need not be sworn; but such persons shall be more than 16 years of age and of suitable intelligence and character. Postmasters shall promptly report any violation of this requirement to the Post Office Department.

§ 92.78 *Transfer and separation of mails.* (a) At connecting points where railroad stations are directly contiguous the company having mails on its trains to be forwarded by a connecting train shall be required to transfer such mails and deliver them to the railroad company operating the connecting train (unless relieved of the service by the Department); first, where the two companies have agents or representatives employed; and, second, where the company having the mails for dispatch makes transfer of baggage or passengers. However, if the train connection is not immediate, the company bringing mails on its trains may deliver them to the agent of the company due to dispatch the mail for proper dispatch by the trains of the latter company. Transfers of mail between connecting trains of steam-railroad routes and cars of electric-railway routes shall be required to be made by the respective companies operating the routes where the railroad company employs an agent and its station is directly contiguous to the tracks of the electric-railway company and the connection is immediate.

(b) Railroad companies will be required to separate mails that received a previous rail haul or are due to receive a subsequent rail haul, received from and dispatched to star, mail messenger and highway post office routes at connecting points. They shall provide the necessary tailboard space for the dispatch and receipt of the mails to and from such routes or deliver them to a point accessible to the vehicles performing this service except where other arrangements have been made by mutual agreement between the Post Office Department and the railroad company.

(c) Railroad companies shall not be required to take the mails from their railroad terminals and stations and deliver them into post offices, postal stations, and postal transportation service terminals, nor take the mails from post offices, postal stations and postal transportation service terminals and deliver them into their railroad terminals and stations where the distance exceeds 80 rods.

§ 92.79 *Duties of mail messenger and railroad representative.* (a) Where a mail messenger is employed by the Department and a railroad representative is on duty, the railroad company may not be required to receive mails from and deliver them into the mail cars or place the mail on mail cranes if the volume of mail is relatively small and can be readily handled by the Post Office Department messenger by hand on one trip. At such a point where mail trains arrive at times when there is no railroad representative on duty, the railroad company shall not be required to place the mails on or take them from trains, and if trucking is necessary under such circumstances the railroad company shall provide and render accessible to the messenger the necessary trucks. The Post Office Department reserves the right, however, in both cases to require the performance of this service by railroad employees at any time during the 24-hour period. (See § 92.72.)

(b) When the Department mail messenger cannot wait for the delayed train without delaying the other mails, the railroad company shall be required to take charge of and dispatch the mails for the delayed train and shall be responsible for the inward mail until it is delivered to the messenger or other authorized representative of the Post Office Department.

(c) In cases where the company's agent cannot give the mail messenger or other carrier of the mail advance information as to the time the train will arrive, the messenger need not wait for the train beyond its scheduled time of arrival. Where the train is reported as being more than two hours late, the messenger need not wait for the arrival of the train. In such cases the messenger may deliver the mail to the company's agent, or other representative, whose duty it shall be to dispatch the mail by proper train and to retain custody of the incoming mail, if any, until it is called for by the messenger. Where the train is reported to arrive within two hours of scheduled time, the messenger should wait for the arrival of the train, but need not wait more than two hours, at the expiration of which time he may turn the mails over to the agent, whose duty shall be the same as in the other cases. At a point where there is no railroad representative on duty and the mail messenger has no means of ascertaining when a delayed train will arrive, it is the duty of the mail messenger to wait at least two hours beyond the scheduled time of arrival of the train, after which time he may return the mail to the post office to be included in the next regular dispatch. In all cases where mail is turned over to the company's agent for dispatch, the company shall be responsible for its proper handling, and the mail messenger shall call for and deliver the incoming mail to the post office as soon as practicable after the arrival of the train unless the train arrives at a late hour of the night and the post office is closed, when the incoming mails may be disposed of as provided for in § 92.72 (a).

§ 92.80 *General superintendents to notify railroads of changes in pouch list.* General superintendents of the Postal Transportation Service shall promptly notify the proper officers of railroad companies of any changes in the list of pouches to be handled by railroad companies.

§ 92.81 *Letter boxes in railroad depots.* When it appears that the public convenience will be subserved, the Post Office Department may authorize railroad companies to place letter boxes in their depots for the receipt of mail matter other than that for local delivery.

§ 92.82 *Train crews not permitted to ride in railway post-office cars.* Train crews shall not be permitted to ride in railway post-office cars while in use, even though the railroad company may furnish a railway post-office car larger than the size authorized.

§ 92.83 *Deductions and fines.* (a) The Post Office Department may impose fines on railroad companies for each of the following delinquencies:

(1) Suffering the mail, or any part of it, to become wet, lost, injured or destroyed, or conveying or keeping it in a place or manner that exposes it to depredation, loss, or injury.

(2) Refusing, after demand, to transport mail by any car, boat or other conveyance which the railroad company runs or is concerned in running on the route.

(3) Leaving or putting aside the mail, or any part of it, for the accommodation of passengers, baggage, express or other matter.

(4) Habitual failure to observe schedules.

(5) Leaving mail which arrives at the station within a reasonable time before the departure of the train or car for which it is intended.

(6) Failure to use the first practicable means of forwarding mail which is delayed en route.

(7) Failure to sound proper signal when approaching mail crane.

(8) Failure to furnish proper accommodations for the handling, storage, and, if necessary, the distribution of mails in depots.

(9) Failure to place railway post-office cars in stations at the time specified by the Post Office Department for the distribution of mails.

(10) Permitting storage cars to accumulate at any point for operation in mail, or mail-express, sections when suitable trains are available for dispatch to destination.

(11) Failure to operate regularly authorized storage cars in the train designated.

(12) Failure to unload storage cars at the point of destination within the time specified by the Post Office Department when such mails are actually delayed.

(b) The fine shall in each case be such sum as the Postmaster General may impose, in view of the gravity of the delinquency and shall be deducted from the railroad company's pay for the service on the route on which the delinquency occurred.

(c) The Postmaster General may fine railroad companies an amount not in excess of the compensation due for the service authorized when the railway post-office car furnished is not supplied with sanitary drinking water, adequate toilet facilities, adequately heated and lighted or when such car is not regularly and thoroughly cleaned, provided, the railroad company has been given the opportunity to correct the condition.

2. In Part 92 rescind the following sections:

§ 92.28 *Mails not to be carried until ordered by department.*
§ 92.29 *Transfer of mail in emergency.*
§ 92.30 *Maintenance of transfer offices by railroads.*
§ 92.32 *Railroads to furnish timetables.*
§ 92.33 *Advance deliveries by railroads.*
§ 92.34 *Arrival of mail late at night.*
§ 92.35 *Dispatch of mail late at night.*
§ 92.36 *Loading of mails.*
§ 92.37 *Holding of trains for loading of mail.*
§ 92.38 *Exchange of mails at nonstop points.*
§ 92.38a *Train stops for dispatch or receipt of mails.*
§ 92.40 *Carriage of mail between post offices and railroad stations.*
§ 92.41 *Railroad employees handling mails regarded as agents of railroads.*
§ 92.42 *Transfer of mails between connecting trains.*
§ 92.43 *Duties of mail messenger and railroad representative.*
§ 92.49 *General superintendents to notify railroads of changes in pouch list.*
§ 92.50 *Letter boxes in railroad depots.*

[SEAL] J. M. DONALDSON,
Postmaster General.

[P. R. Doc. 50-12576; Filed, Dec. 29, 1950; 8:58 a. m.]

PART 127—INTERNATIONAL POSTAL SERVICE: POSTAGE RATES, SERVICE AVAILABLE, AND INSTRUCTIONS FOR MAILING

CANADA AND INDIA

a. In § 127.227 *Canada* (39 CFR 127.227; 15 F. R. 4499) amend paragraph (b) (6) by striking out subdivisions (iii) and (iv) and by inserting the following in lieu thereof:

(iii) Occasional commercial shipments addressed to individuals are

exempted from quota and do not require special permission for importation, provided the value for duty does not exceed $10.00.

(iv) Before mailing any package or parcel to Canada, senders should assure themselves that the contents will be admitted, and must endorse the wrapper "Importation into Canada authorized," "Bona fide gift", or "Wedding gift", as the case may be. It is important that the value of the contents be carefully indicated on the customs declaration.

(v) Interested patrons may obtain further information concerning articles whose importation is prohibited or restricted from the Canadian government departments named above, from the British Commonwealth Division, Office of International Trade, Department of Commerce, Washington 25, D. C., or from any field office of that Department.

b. In § 127.278 *India* (39 CFR 127.278) make the following changes:

1. Amend paragraph (a) (6) by the addition of subdivision (iv) to read as follows:

(iv) Addressees in India are required to obtain import licenses in many cases in order to take delivery of commercial shipments.

2. Amend paragraph (b) (4) by the insertion of a new subdivision, to be designated (ii-a), in the text between (ii) and (iii) to read as follows:

(ii-a) Addressees in India are required in many cases to obtain import licenses in order to take delivery of commercial shipments.

(R. S. 161, 396, secs. 304, 309, 42 Stat. 24, 25; 5 U. S. C. 22, 369; and the terms of postal conventions and agreements entered into pursuant to R. S. 398, 48 Stat. 943; 5 U. S. C. 372)

[SEAL] J. M. DONALDSON,
Postmaster General.

[F. R. Doc. 50-12483; Filed, Dec. 29, 1950; 8:47 a. m.]

TITLE 43—PUBLIC LANDS: INTERIOR

Chapter I—Bureau of Land Management, Department of the Interior

Appendix—Public Land Orders

[Public Land Order 694]

COLORADO, IDAHO, MONTANA, AND UTAH

RESERVATION OF LANDS WITHIN NATIONAL FORESTS FOR ADMINISTRATIVE SITES OR RECREATIONAL AREAS

By virtue of the authority vested in the President by the act of June 4, 1897, 30 Stat. 34, 36 (16 U. S. C. 473), and otherwise, and pursuant to Executive Order No. 9337 of April 24, 1943, it is ordered as follows:

Subject to valid existing rights, the following-described public lands in Colorado, Idaho, Montana, and Utah within certain national forests as hereinafter designated are hereby withdrawn from all forms of appropriation under the public-land laws, including the mining laws, but not the mineral-leasing laws, and reserved as administrative sites or recreation areas as indicated:

COLORADO

NEW MEXICO PRINCIPAL MERIDIAN

Rio Grande National Forest; Wolf Creek Pass Winter Sports Area

T. 37 N., R. 2 E.,
Sec. 5, lots 3, 4, S½NW¼, and W½SW¼;
Sec. 6, lots 1, 2, 3, S½NE¼, SE¼NW¼, E½SW¼, and SE¼;
Sec. 7, N½NE¼.
T. 38 N., R. 2 E.,
Sec. 28, SW¼SW¼, E½SW¼ and W½SE¼;
Sec. 29, SE¼SE¼;
Sec. 31, SE¼SW¼, SW¼SE¼ and E½SE¼;
Sec. 32, E½NE¼, SW¼NE¼, SE¼NW¼, SW¼, and N½SE¼;
Sec. 33, W½NW¼.
The areas described aggregate 1,680.49 acres.

IDAHO

BOISE MERIDIAN

Clearwater National Forest; Cedars Administrative Site

T. 41 N., R. 11 E.,
Sec. 28, N½, N½SW¼, SW¼SW¼, and NW¼SE¼.
The area described contains 480 acres.

St. Joe National Forest; Red Ives Administrative Site

T. 43 N., R. 9 E.,
Sec. 20, NW¼SW¼NE¼, S½SW¼NE¼, S½SE¼NE¼, and W½SE¼;
Sec. 29, NW¼NE¼, N½SW¼NE¼, and SE¼SW¼NE¼;
Sec. 31, S½N½NE¼, N½S½NE¼, SW¼SW¼NE¼;
Sec. 32, NE¼NW¼NE¼, S½NW¼NE¼, N½SW¼NE¼, S½N½NW¼, and N½S½NW¼.
The areas described aggregate 420 acres.

Targhee National Forest; Buffalo Administrative Site

T. 13 N., R. 43 E.,
Sec. 27, lots 7, 8, SE¼SW¼, and W½SE¼.
The area described contains 183.70 acres.

MONTANA

PRINCIPAL MERIDIAN

Lewis and Clark National Forest; Crystal Lake Recreation Area

T. 12 N., R. 17 E.,
Sec. 13, unsurveyed, S½SE¼;
Sec. 24, unsurveyed, E½, E½NW¼, and NE¼SW¼.
T. 12 N., R. 18 E., unsurveyed,
Sec. 19, W½NW¼NW¼, S½NW¼, and SW¼.
The areas described aggregate approximately 780 acres.

UTAH

SALT LAKE MERIDIAN

Cache National Forest; Elk Valley Administrative Site

T. 12 N., R. 4 E.,
Sec. 33, SE¼.
The area described contains 160 acres.

This order shall take precedence over, but not otherwise affect, the existing reservations of the lands involved for national-forest purposes.

OSCAR L. CHAPMAN,
Secretary of the Interior.

DECEMBER 26, 1950.

[F. R. Doc. 50-12478; Filed, Dec. 29, 1950; 8:46 a. m.]

TITLE 49—TRANSPORTATION

Chapter I—Interstate Commerce Commission

[S. O. 848, Amdt. 3]

PART 95—CAR SERVICE

REFRIGERATOR CARS FOR TRANSPORTING COTTON

At a session of the Interstate Commerce Commission, Division 3, held at its office in Washington, D. C., on the 26th day of December A. D. 1950.

Upon further consideration of Service Order No. 848 (15 F. R. 1222), and good cause appearing therefor: It is ordered, that:

Section 95.848 *Refrigerator cars for transporting cotton*, of Service Order No. 848 be, and it is hereby further amended by substituting the following paragraph (d) for paragraph (d) thereof:

(d) *Expiration date.* This section shall expire at 11:59 p. m., March 31, 1951, unless otherwise modified, changed, suspended, or annulled by order of this Commission.

Effective date: This amendment shall become effective at 11:59 p. m., December 31, 1950.

It is further ordered, that a copy of this amendment and direction be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and per diem agreement under the terms of that agreement; and that notice of this order be given to the general public by depositing a copy in the office of the Secretary of the Commission at Washington, D. C., and by filing it with the Director, Division of the FEDERAL REGISTER.

(Sec. 12, 24 Stat. 383, as amended; 49 U. S. C. 12. Interprets or applies sec. 1, 24 Stat. 379, as amended; 49 U. S. C. 1)

By the Commission, Division 3.

[SEAL] W. P. BARTEL,
Secretary.

[F. R. Doc. 50-12574; Filed, Dec 29, 1950; 9:00 a. m.]

PROPOSED RULE MAKING

DEPARTMENT OF AGRICULTURE

Bureau of Entomology and Plant Quarantine

[7 CFR, Part 301]

PINK BOLLWORM QUARANTINE IN LOUISIANA, TEXAS AND OKLAHOMA

NOTICE OF PUBLIC HEARING

Notice of public hearing and of proposed rule making on extending the quarantine on account of pink bollworm to the State of Louisiana and regulating certain areas therein and on extending the regulated areas under said quarantine in the States of Texas and Oklahoma.

Notice is hereby given in accordance with section 8 of the Plant Quarantine Act of August 20, 1912, as amended (37 Stat. 318, as amended; 7 U. S. C. 161), and section 4 (a) of the Administrative Procedure Act (60 Stat. 238; 5 U. S. C. 1003 (a)), as follows:

The Secretary of Agriculture has information that the pink bollworm (Poctinophora gossypiella Saund.), a dangerous insect not heretofore widely prevalent or distributed within or throughout the United States, but which previously has been found to exist in certain parts of the States of Arizona, New Mexico, Oklahoma, and Texas, has recently been discovered in certain parts of the State of Louisiana.

It is therefore proposed under the authority of said section 8 of the Plant Quarantine Act to amend the Pink Bollworm Quarantine (7 CFR 301.52) to quarantine the State of Louisiana because of pink bollworm and to amend the regulations supplemental to said quarantine (7 CFR and Supp. 301.52–1 et seq., as amended, 15 F. R. 164) to designate as regulated areas the parishes of Calcasieu, Cameron, Evangeline, and Vermilion and possibly also the parishes of Acadia, Allen, Avoyelles, Beauregard, Iberia, Jefferson Davis, Lafayette, Pointe Coupee, Rapides, St. Landry, St. Martin, and Vernon. Prohibitions and restrictions as prescribed in said regulations would thus be made applicable to the movement from such regulated areas in the State of Louisiana into or through any other State, Territory, or District of the United States of the following:

(1) Cotton and wild cotton, including all parts of both cotton and wild cotton plants; seed cotton; cotton lint; linters; and all other forms of unmanufactured cotton fiber, gin waste, cottonseed, cottonseed hulls, cottonseed cake, and meal; (2) okra, including all parts of the plants; (3) bagging and other containers and wrappers of cotton and cotton products; (4) railway cars, boats, and other means of transportation which have been used in conveying regulated cotton products or which are fouled with such products; and (5) when contaminated with regulated cotton products, any other commodities, including farm products, farm household goods, and farm equipment.

The Secretary of Agriculture also has information that infestations of the pink bollworm were recently discovered in the following counties in the presently quarantined States of Texas and Oklahoma that heretofore have not been designated as regulated areas in said regulations, and it is therefore proposed, under the authority of said section 8 of the Plant Quarantine Act to amend said regulations so as to include such counties within the regulated areas:

TEXAS

Archer.	Kendall.
Austin.	Kerr.
Bandera.	Kimble.
Bastrop.	Kinney.
Bell.	Lavaca.
Blanco.	Lee.
Bosque.	Liberty.
Brazoria.	Limestone.
Chambers.	Llano.
Clay.	McLennan.
Colorado.	Milam.
Comal.	Orange.
Edwards.	Palo Pinto.
Falls.	Real.
Fayette.	Somervell.
Fort Bend.	Stephens.
Gillespie.	Sutton.
Hill.	Travis.
Hood.	Val Verde.
Jack.	Williamson.
Jefferson.	Young.
Johnson.	

OKLAHOMA

Comanche.	Jefferson.
Cotton.	Stephens.

Following discovery of the abovementioned infestations the States of Texas and Oklahoma, as well as the State of Louisiana, promptly issued State quarantines to provide safeguards on the movement of host material from the infested areas.

A public hearing will be held before a representative of the Bureau of Entomology and Plant Quarantine in the Third Floor Courtroom, United States Custom and Courthouse Building, Memphis, Tennessee, at 10:00 a. m., January 11, 1951, at which hearing any interested party may appear and be heard, either in person or by attorney, on the aforesaid proposals. Any interested person who desires to submit written data, views, or arguments on the proposals may do so by filing the same with the Chief of the Bureau of Entomology and Plant Quarantine, United States Department of Agriculture, Washington 25, D. C., on or before January 9, 1951.

Done at Washington, D. C., this 27th day of December 1950.

[SEAL] CHARLES F. BRANNAN,
Secretary of Agriculture.

[F. R. Doc. 50-12407; Filed, Dec. 29, 1950; 8:45 a. m.]

Production and Marketing Administration

[7 CFR, Part 932]

[Docket No. AO-33-A 16]

HANDLING OF MILK IN FORT WAYNE, INDIANA, MARKETING AREA

NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT TO TENTATIVE MARKETING AGREEMENT AND TO ORDER, AS AMENDED

Pursuant to the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.) and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR, Part 900), notice is hereby given of a public hearing to be held in Room 265, Federal Building, Fort Wayne, Indiana, beginning at 10:00 a. m., c. s. t., January 3, 1951, for the purpose of receiving evidence with respect to economic and emergency conditions in the marketing area specified above which relate to the proposed amendment hereinafter set forth, or appropriate modifications thereof, to the tentative marketing agreement heretofore approved by the Secretary of Agriculture and to the order, as now in effect, regulating the handling of milk in such marketing area. The proposed amendment has not received the approval of the Secretary of Agriculture.

Proposed by Wayne Co-operative Milk Producers, Inc.:

Amend §§ 932.51 and 932.52 to establish differentials for Class I milk and Class II milk over basic formula prices for the months of January, February and March, 1951, equivalent to those which prevailed in December 1950, which were: $0.80 for Class I milk and $0.65 for Class II milk.

Copies of this notice of hearing, the said order as now in effect, and the said tentative marketing agreement, may be procured from the Market Administrator, 407 Strauss Building, Fort Wayne, Indiana, or from the Hearing Clerk, Room 1353, South Building, United States Department of Agriculture, Washington 25, D. C., or may be there inspected.

Dated: December 27, 1950.

[SEAL] JOHN I. THOMPSON,
Assistant Administrator.

[F. R. Doc. 50-12522; Filed, Dec. 29, 1950; 8:53 a. m.]

[7 CFR, Part 943]

[Docket No. AO 231]

HANDLING OF MILK IN NORTH TEXAS MARKETING AREA

NOTICE OF HEARING ON PROPOSED MARKETING AGREEMENT AND ORDER

Pursuant to the provisions of the Agricultural Marketing Agreement Act

of 1937, as amended (7 U. S. C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR, Part 900), notice is hereby given of a public hearing to be held at Texas State Fairgrounds, Dallas, Texas, beginning at 10:00 a. m., c. s. t., January 31, 1951. This public hearing is for the purpose of receiving evidence with respect to a proposed marketing agreement and order, regulating the handling of milk in the North Texas marketing area, the provisions of which are hereinafter set forth, and any modifications thereof. The proposed marketing agreement and order have not received the approval of the Secretary of Agriculture, and at the hearing evidence will be received relative to all aspects of the marketing conditions which are dealt with by the proposed marketing agreement and order and any modification thereof. The provisions of the proposals for a marketing agreement and order, heretofore filed with the undersigned, are as follows:

Marketing agreement and order proposed by the North Texas Producers Association, Arlington, Texas:

DEFINITIONS

§ 943.1 *Act.* "Act" means Public Act No. 10, 73d Congress, as amended, and as reenacted and amended by the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.).

§ 943.2 *Secretary.* "Secretary" means the Secretary of Agriculture or other officer or employee of the United States authorized to exercise the powers or to perform the duties of the said Secretary of Agriculture.

§ 943.3 *Department.* "Department" means the United States Department of Agriculture or such other Federal agency authorized to perform the price reporting functions specified herein.

§ 943.4 *Person.* "Person" means any individual, partnership, corporation, association, or any other business unit.

§ 943.5 *Cooperative association.* "Cooperative association" means any cooperative marketing association of producers which the secretary determines, after application by the Association:

(a) To be qualified under the provisions of the Act of Congress of February 18, 1922, as amended, known as the "Capper-Volstead Act"; and,

(b) To have full authority in the sale of milk of its members and to be engaged in making collective sales or marketing milk or its products for its members.

§ 943.6 *North Texas marketing area.* "North Texas marketing area," hereinafter called the marketing area, means all territory within the corporate limits of Dallas, Fort Worth, Paris, Dublin, Terrell, Denison, Sherman, Gainesville, Tyler, Decatur, Denton, McKinney, Cleburne, Longview, Waxahachie, and Commissioners Precinct Number 1, Ellis County, all in the State of Texas.

§ 943.7 *Approved plant.* "Approved plant" means:

(a) A milk plant approved by any health authority having jurisdiction in the marketing area from which milk, skim milk, buttermilk, flavored milk, flavored milk drinks, or cream are disposed of for fluid consumption in the marketing area on wholesale or retail routes (including plant stores); or,

(d) A milk plant approved by any health authority having jurisdiction in the marketing area which receives milk from producers, as herein defined, and which serves as a receiving station for a plant specified in paragraph (a) of this section.

§ 943.8 *Unapproved plant.* "Unapproved plant" means any milk processing or distributing plant which is not an approved plant.

§ 943.9 *Handler.* "Handler" means:

(a) Any person in his capacity as the operator of an approved plant; or

(b) Any cooperative association with respect to the milk of any producer which it causes to be diverted to an unapproved plant for the account of such cooperative association.

§ 943.10 *Producer.* "Producer" means any person, other than a producer-handler, who produces milk which is received at an approved plant: *Provided*, That such milk is produced under a dairy farm permit or rating issued by any health authority having jurisdiction in the marketing area for the production of milk to be disposed of for consumption as Grade A milk. This definition shall include any such person who is regularly classified as a producer but whose milk is caused to be diverted by a handler to an unapproved plant, and milk so diverted shall be deemed to have been received at an approved plant by the handler who causes it to be diverted. This definition shall not include a person with respect to milk produced by him which is received at a plant operated by a handler who is subject to another Federal marketing order and who is partially exempt from the provisions of this part, pursuant to § 943.61.

§ 943.11 *Producer milk.* "Producer milk" means all skim milk and butterfat in milk produced by a producer which is purchased or received by a handler either directly from producers or from other handlers.

§ 943.12 *Other source milk.* "Other source milk" means all milk and butterfat other than that contained in producer milk.

§ 943.13 *Producer-handler.* "Producer-handler" means any person who produces milk and operates an approved plant, but who receives no milk from producers.

MARKET ADMINISTRATOR

§ 943.20 *Designation.* The agency for the administration hereof shall be a market administrator, selected by the Secretary, who shall be entitled to such compensation as may be determined by, and shall be subject to removal at the discretion of, the Secretary.

§ 943.21 *Powers.* The market administrator shall have the following powers with respect to this part:

(a) To administer its terms and provisions;

(b) To receive, investigate, and report to the Secretary complaints of violations;

(c) To make rules and regulations to effectuate its terms and provisions; and,

(d) To recommend amendments to the Secretary.

§ 943.22 *Duties.* The market administrator shall perform all duties necessary to administer the terms and provisions of this order, including but not limited to the following:

(a) Within 30 days following the date on which he enters upon his duties, or such lesser period as may be prescribed by the Secretary, execute and deliver to the Secretary a bond effective as of the date on which he enters upon such duties and conditioned upon the faithful performance of such duties, in an amount and with surety thereon satisfactory to the Secretary;

(b) Employ and fix the compensation of such persons as may be necessary to enable him to administer its terms and provisions;

(c) Obtain a bond in reasonable amount and with reasonable surety thereon covering each employee who handles funds entrusted to the market administrator;

(d) Pay out of funds provided by § 943.110 the cost of his bond and of the bonds of his employees, his own compensation, and all other expenses (except those incurred under § 945.100) necessarily incurred by him in the maintenance and functioning of his office and in the performance of his duties;

(e) Keep such books and records as will clearly reflect the transactions provided for herein, and upon request by the Secretary, surrender the same to such other person as the Secretary may designate;

(f) Submit his books and records to examination by the Secretary and furnish such information and reports as may be requested by the Secretary;

(g) Audit all reports and payments by each handler by inspection of such handler's records and of the records of any other handler or person upon whose utilization the classification of skim milk or butterfat for such handler depends;

(h) Publicly announce, at his discretion, by posting in a conspicuous place in his office and by such other means as he deems appropriate, the name of any person who, within 10 days after the day upon which he is required to perform such acts, has not:

(1) Made reports pursuant to §§ 943.30 to 943.33, inclusive;

(2) Maintained adequate records and facilities pursuant to § 943.33; or

(3) Made payments pursuant to §§ 943.80 to 943.85, inclusive.

(i) On or before the 12th day after the end of each month, report to each cooperative association which so requests the amount and class utilization of milk caused to be delivered by such cooperative association, either directly or from producers who are members of such cooperative association, to each handler to whom the cooperative association sells milk. For the purpose of this

report, the milk caused to be so delivered by a cooperative association shall be prorated to each class in the proportion that the total receipts of producer milk by such handler were used in each class;

(j) Publicly announce by posting in a conspicuous place in his office and by such other means as he deems appropriate the prices determined for each month as follows:

(1) On or before the 5th day of each month the minimum prices for Class I milk, pursuant to § 943.51 (a) and the Class I butterfat differential pursuant to § 943.52 (a), both for the current month; and the minimum price for Class II milk pursuant to § 943.51 (b) and the Class II butterfat differential pursuant to § 943.52 (b), both for the preceding month; and,

(2) On or before the 12th day of each month, the uniform prices computed pursuant to § 943.71 and the butterfat differential computed pursuant to § 943.81, both applicable to milk delivered during the preceding month; and,

(k) Prepare and disseminate to the public such statistics and information as he deems advisable and as do not reveal confidential information.

(l) Furnish to a cooperative association for its members the data furnished pursuant to § 943.30 (a).

(m) The market administrator, in order to insure the payments by handlers required under the provisions of § 943.80 of this order, shall require all handlers subject to the order to post a bond in an amount not exceeding twice the estimated amount of the payments to be made to producers for any delivery period and require such sureties on said bond as will satisfy the market administrator.

REPORTS, RECORDS AND FACILITIES

§ 943.30 *Reports of receipts and utilization.* On or before the 7th day after the end of each month, each handler, except a producer-handler, shall report to the market administrator in the detail and on forms prescribed by the market administrator as follows:

(a) The quantities of skim milk and butterfat contained in milk received from each producer;

(b) The quantities of skim milk and butterfat contained in (or used in the production of) receipts from other handlers;

(c) The quantities of skim milk and butterfat contained in receipts of other source milk (except Class II products disposed of in the form in which received without further processing or packaging by the handler);

(d) The utilization of all skim milk and butterfat required to be reported pursuant to this section;

(e) The disposition of Class I products on routes wholly outside the marketing area; and,

(f) Such other information with respect to receipts and utilization as the market administrator may prescribe.

§ 943.31 *Payroll reports.* On or before the 20th day of each month, each handler shall submit to the market administrator his producer payroll for deliveries of the preceding month, which shall show:

(a) The total pounds of milk received from each producer and cooperative association and the total pounds of butterfat contained in such milk;

(b) The amount of payment to each producer and cooperative association; and,

(c) The nature and amount of any deductions or charges involved in such payments.

§ 943.32 *Other reports.* (a) Each producer-handler shall make reports to the market administrator at such time and in such manner as the market administrator may prescribe.

(b) Each handler who causes milk to be diverted to an unapproved plant shall, prior to such diversion, report to the market administrator and to the cooperative association of which such producer is a member his intention to divert such milk, the proposed date or dates of such diversion, and the plant to which such milk is to be diverted.

§ 943.33 *Records and facilities.* Each handler shall maintain and make available to the market administrator or to his representative during the usual hours of business such accounts and records of his operations and such facilities as are necessary for the market administrator to verify or establish the correct data with respect to:

(a) The receipts and utilization of all receipts of producer milk and other source milk;

(b) The weights and tests for butterfat and other content of all milk, skim milk, cream and milk products handled;

(c) Payments to producers and cooperative associations; and,

(d) The pounds of skim milk and butterfat contained in or represented by all milk, skim milk, cream and milk products on hand at the beginning and end of each month.

§ 943.34 *Retention of records.* All books and records required under this order to be made available to the market administrator shall be retained by the handler for a period of three years to begin at the end of the month to which such books and records pertain: *Provided*, That if, within such three-year period, the market administrator notifies the handler in writing that the retention of such books and records, or of specified books and records, is necessary in connection with a proceeding under section 8 (c) (15) (A) of the act or a court action specified in such notice, the handler shall retain such books and records, or specified books and records, until further written notification from the market administrator. In either case, the market administrator shall give further written notification to the handler promptly, upon the termination of the litigation or when the records are no longer necessary in connection therewith.

CLASSIFICATION

§ 943.40 *Skim milk and butterfat to be classified.* All skim milk and butterfat received within the month by a handler and which is required to be reported pursuant to § 943.30 shall be classified by the market administrator pursuant to the provisions of §§ 943.41 to 943.45, inclusive.

§ 943.41 *Classes of utilization.* Subject to the conditions set forth in §§ 943.42 and 943.43, the classes of utilization shall be as follows:

(a) Class I milk shall be all skim milk (including reconstituted skim milk) and butterfat disposed of in the form of milk, skim milk, buttermilk, flavored milk drinks, cream, cultured sour cream, aerated products containing milk or cream, cottage cheese, any mixture (except bulk ice cream mix) of cream and milk or skim milk, and all skim milk and butterfat not specifically accounted for under paragraph (b) of this section; and any other product containing skim milk or butterfat not specifically accounted for in paragraph (b) of this section which the health regulations shall now or hereafter require to be made fom Grade A milk.

(b) Class II milk shall be all skim milk and butterfat:

(1) Used to produce any product other than those specified in paragraph (a) of this section;

(2) Disposed of for livestock feed;

(3) In shrinkage of other source milk; and,

(4) In inventory variations of milk, skim milk and cream.

§ 943.42 *Responsibility of handlers and reclassification of milk.* (a) All skim milk and butterfat shall be Class I milk unless the handler who first receives such skim milk or butterfat can prove to the market administrator that such skim milk or butterfat should be classified otherwise.

(b) Any skim milk or butterfat (except that transferred to a producer-handler) shall be reclassified if verification by the market administrator discloses that the original classification was incorrect.

§ 943.43 *Transfers.* Skim milk or butterfat disposed of by a handler either by transfer or diversion shall be classified:

(a) As Class I milk if transferred or diverted in the form of milk, skim milk or cream, to the approved plant of another handler (except a producer-handler), unless utilization in Class II is mutually indicated in writing to the market administrator by both handlers on or before the 7th day after the end of the month within which such transaction occurred: *Provided*, That the skim milk or butterfat so assigned to Class II shall be limited to the amount thereof remaining in Class II in the plant of the transferee-handler after the subtraction of other source milk, pursuant to § 943.45, and any additional amounts of such skim milk or butterfat shall be assigned to Class I: *And provided further*, That if either or both handlers have received other source milk the skim milk or butterfat so transferred or diverted shall be classified at both plants so as to allocate the greatest possible Class I utilization to producer milk.

(b) As Class I milk, if transferred or diverted to a producer-handler in the form of milk, skim milk, or cream.

(c) As Class I milk, if transferred or diverted in the form of milk or skim milk to an unapproved plant located more than 100 miles from the approved plant by the shortest highway distance as determined by the market administrator.

(d) As Class I milk, if transferred in the form of cream under Grade A certification to an unapproved plant located more than 100 miles from the marketing area, and as Class II milk if so transferred without Grade A certification.

(e) (1) As Class I milk if transferred or delivered in the form of milk, skim milk, or cream to an unapproved plant located not more than 100 miles from the approved plant, and from which fluid milk is disposed of on wholesale or retail routes unless all the following conditions are met:

(i) The market administrator is permitted to audit the records of such unapproved plant; and,

(ii) Such unapproved plant receives milk from dairy farmers who the market administrator determines constitute its regular source of supply for Class I milk.

(2) If these conditions are met, the market administrator shall classify such milk as reported by the handler subject to verification as follows:

(i) Determine the use of all skim milk and butterfat at such unapproved plant; and

(ii) Allocate the skim milk and butterfat so transferred or diverted to the highest use classification remaining after subtracting in series beginning with the highest use classification, the skim milk and butterfat in milk received at the unapproved plant directly from dairy farmers.

(f) As Class II milk, if transferred or diverted in the form of milk, skim milk, or cream to an unapproved plant located not more than 100 miles from the approved plant and from which fluid milk is not disposed of on wholesale or retail routes.

§ 943.44 *Computation of the skim milk and butterfat in each class.* For each month, the market administrator shall correct for mathematical and for other obvious errors the monthly report submitted by each handler and shall compute the pounds of skim milk and butterfat in Class I milk and Class II milk for such handler.

§ 943.45 *Allocation of skim milk and butterfat classified.* After making the computations pursuant to § 943.44, the market administrator shall determine the classification of milk received from producers as follows:

(a) Skim milk shall be allocated in the following manner:

(1) Subtract from the pounds of skim milk in Class II the pounds of skim milk in other source milk: *Provided*, That if the receipts of skim milk in other source milk are greater than the remaining pounds of skim milk in Class II, an amount equal to the difference shall be subtracted from the pounds of skim milk in Class I;

(2) Subtract from the remaining pounds of skim milk in each class the skim milk received from other handlers according to its classification as determined pursuant to § 943.43 (a);

(3) If the remaining pounds of skim milk in both classes exceed the pounds of skim milk received from producers, subtract such excess from the remaining pounds of skim milk in series beginning with Class II milk. Any amount so subtracted shall be called "overage."

(b) Butterfat shall be allocated in accordance with the same procedure outlined for skim milk in paragraph (a) of this section.

(c) Determine the weighted average butterfat content of Class I and Class II milk computed pursuant to paragraphs (a) and (b) of this section.

MINIMUM PRICES

§ 943.50 *Basic formula price to be used in determining Class I prices.* The basic formula price to be used in determining the price per hundredweight of Class I milk shall be the highest of the prices computed pursuant to paragraphs (a) and (b) of this section and § 943.51 (b).

(a) The average of the basic or field prices per hundredweight reported to have been paid or to be paid for milk of 3.5 percent butterfat content received from farmers during the month at the following plants or places for which prices have been reported to the market administrator or to the Department, divided by 3.5 and multiplied by 4.0:

Present Operator and Location

Borden Co., Mount Pleasant, Mich.
Carnation Co., Sparta, Mich.
Pet Milk Co., Hudson, Mich.
Pet Milk Co., Wayland, Mich.
Pet Milk Co., Coopersville, Mich.
Borden Co., Greenville, Wis.
Borden Co., Black Creek, Wis.
Borden Co., Orfordville, Wis.
Borden Co., New London, Wis.
Carnation Co., Chilton, Wis.
Carnation Co., Berlin, Wis.
Carnation Co., Richland Center, Wis.
Carnation Co., Oconomowoc, Wis.
Carnation Co., Jefferson, Wis.
Pet Milk Co., New Glarus, Wis.
Pet Milk Co., Belleville, Wis.
White House Milk Co., Manitowoc, Wis.
White House Milk Co., West Bend, Wis.

(b) The price per hundredweight computed by adding together the plus values pursuant to subparagraphs (1) and (2) of this paragraph:

(1) From the simple average as computed by the market administrator of the daily wholesale selling prices (using the midpoint of any price range as one price) per pound of Grade A (92-score) bulk creamery butter per pound at Chicago, as reported by the Department during the month, subtract 3 cents, add 20 percent thereof, and multiply by 4.0.

(2) From the simple average as computed by the market administrator of the weighted averages of carlot prices per pound for nonfat dry milk solids, spray and roller process, respectively, for human consumption, f. o. b. manufacturing plants in the Chicago area, as published for the period from the 26th day of the preceding month through the 25th day of the current month by the Department, deduct 5.5 cents, multiply by 8.5, and then multiply by 0.96.

§ 943.51 *Class prices.* Subject to the provisions of § 943.52, the minimum prices per hundredweight to be paid by each handler for milk received at his plant from producers during the month shall be as follows:

(a) *Class I milk.* The basic formula price plus $2.25 during the months of April, May and June, and plus $2.70 during all other months: *Provided*, That for each of the months of October, November, December, and January such price shall not be less than that for the preceding month, and that for each of the months of April, May and June such price shall not be more than that for the preceding month.

(b) *Class II milk.* The average of the basic or field prices reported to have been paid or to be paid for ungraded milk of 4.0 percent butterfat content received from farmers during the month at the following plants or places for which prices have been reported to the market administrator or to the Department:

Present Operator and Location

Carnation Co., Sulphur Springs, Tex.
Farmers Marketing Cooperative Association, Muenster, Tex.
South Texas Processing Plant, LaGrange, Tex.
Lamar Creamery, Paris, Tex.

§ 943.52 *Butterfat differentials to handlers.* If the average butterfat content of the milk of any handler allocated to any class pursuant to § 943.45 is more or less than 4.0 percent, there shall be added to the respective class price, computed pursuant to § 943.51, for each one-tenth of 1 percent that the average butterfat content of such milk is above 4.0 percent, or subtracted for each one-tenth of 1 percent that such average butterfat content is below 4.0 percent, an amount equal to the butterfat differential computed by multiplying the simple average, as computed by the market administrator, of the daily wholesale selling price per pound (using the midpoint of any price range as one price) of Grade A (92-score) bulk creamery butter at Chicago as reported by the Department during the preceding month by the applicable factor listed below and dividing the result by 10:

(a) *Class I milk.* Multiply by 1.25;
(b) *Class II milk.* Multiply by 1.15.

APPLICATION OF PROVISIONS

§ 943.60 *Producer-handlers.* Sections 943.40 to 943.45, 943.50 to 943.52, 943.70, 943.71, 943.80 to 943.84, 943.90 to 943.92, and 943.100 to 943.110 shall not apply to a producer-handler.

§ 943.61 *Handlers subject to other orders.* In the case of any handler who the Secretary determines disposes of a greater portion of his milk as Class I milk in another marketing area regulated by another milk marketing agreement or order issued pursuant to the Act, the provisions of this part shall not apply except as follows:

(a) The handler shall, with respect to the total receipts of skim milk and butterfat, make reports to the market administrator at such time and in such manner as the market administrator may require and allow verification of

such reports by the market administrator.

(b) If the price which such handler is required to pay under the other Federal order to which he is subject for skim milk and butterfat which would be classified in Class I milk under this order is less than the price provided by this order, such handler shall pay to the market administrator for deposit into the producer-settlement fund (with respect to all skim milk and butterfat disposed of as Class I milk within the marketing area) an amount equal to the difference between the value of such skim milk or butterfat as computed pursuant to this order and its value as determined pursuant to the other order to which he is subject.

§ 943.62 The market administrator is hereby authorized, empowered and directed to make an administrative determination from the records of the handlers in this marketing area and the producers association in this marketing area of the daily base and monthly base of all producers on the market, if necessary in order to effect the provisions of § 943.91 during the first year of its operation.

§ 943.63 *Other source milk.* For any other source skim milk or butterfat subtracted from Class I pursuant to the provisions of § 943.45, the market administrator in determining the net pool obligation of the handler pursuant to this order shall add an amount equal to the difference between the value of such skim milk and butterfat at the Class I and at the Class II price, unless such handler can prove to the satisfaction of the market administrator that such other source skim milk and butterfat was utilized only to the extent that producer milk was not available.

§ 943.64 The market administrator may prescribe reasonable rules and regulations governing the testing technique which shall be utilized in testing producer milk to determine the butterfat content thereof as a basis for the computations and payments to be made pursuant to the provisions of this part.

DETERMINATION OF UNIFORM PRICE

§ 943.70 *Computation of value of milk.* The value of milk received during each month by each handler from producers shall be a sum of money computed by the market administrator by multiplying the pounds of such milk in each class by the applicable class prices and adding together the resulting amounts: *Provided*, That if the handler had overage of either skim milk or butterfat, there shall be added to the above values an amount computed by multiplying the pounds of overage deducted from each class pursuant to § 943.45 by the applicable class prices.

§ 943.71 *Computation of uniform price.* For each month the market administrator shall compute the uniform price per hundredweight for milk of 4.0 percent butterfat content received from producers as follows:

(a) Combine into one total the values computed pursuant to paragraph (a) of this section for all handlers who made the reports prescribed in § 943.30 and who made the payments pursuant to §§ 943.80 and 943.84 for the preceding month.

(b) Add not less than one-half of the cash balance on hand in the producer-settlement fund, less the total amount of the contingent obligations to handlers pursuant to § 943.84.

(c) Subtract if the average butterfat content of the milk included in these computations is greater than 4.0 percent, or add if such average butterfat content is less than 4.0 percent an amount computed by multiplying the amount by which the average butterfat content of such milk varies from 4.0 percent by the butterfat differential computed pursuant to § 943.81 and multiplying the resulting figure by the total hundredweight of such milk;

(d) Subtract not less than 4 cents nor more than 5 cents per hundredweight of milk included in these computations.

(e) Compute the total quantity of milk which represents the delivered bases of producers and which is included in the computation made pursuant to paragraph (a) of this section.

(f) During the period of time from February 1 through September 30 of each year, compute the total value of the milk which is in excess of the delivered base of producers computed pursuant to paragraph (e) of this section and which is included in the computation pursuant to paragraph (a) of this section as follows:

(1) During the period of time from February 1 through September 30 of each year, determine the classification of milk in excess of base by allocating such milk first to Class II and then to Class I until all such milk has been classified;

(2) Multiply the total pounds of excess milk allocated to each class by the appropriate class prices provided in § 943.51;

(3) Add together the resulting amounts.

(g) Compute the total value of the milk represented by the delivered bases of producers by subtracting the value obtained in paragraph (f) of this section from the value obtained in paragraph (a) of this section.

(h) During the period of time from February 1 through September 30 of each year, divide the result obtained in paragraph (g) of this section by the quantity of milk represented by the delivered bases of producers as determined in paragraph (e) of this section. This result will be known as the uniform price per hundredweight for such month for base milk of producers containing 4.0 percent butterfat.

(i) During the period of time from February 1 through September 30 of each year, divide the result obtained in paragraph (f) of this section by the total hundredweight of milk in excess of the delivered base of producers. This result shall be known as the "excess price" for each month.

(j) On or before the 12th day after the end of each month, notify all handlers of these computations, of the uniform price per hundredweight of base milk and the excess price per hundredweight, computed pursuant to this paragraph.

§ 943.80 *Time and method of payment.* (a) On or before the 15th day after the end of the month during which the milk was received, after deducting the amount of the payments made pursuant to paragraph (b) of this section, subject to the butterfat differential computed pursuant to § 943.81, for milk purchased or received from producers by each handler during such month, such handler shall make payment as follows:

(1) To each producer, except as set forth in paragraph (3) of this paragraph, not less than the uniform price per hundredweight, computed pursuant to § 943.71 (h) for that quantity of milk received from such producer not in excess of such producer's base; and,

(2) To each producer, except as set forth in paragraph (3) of this paragraph, not less than the excess price, computed pursuant to § 943.71 (i), for that quantity of milk received from such producer in excess of such producer's base; and,

(3) To a cooperative association for milk which is caused to be delivered to a handler from producers and for which such cooperative association is authorized to collect payments, if the cooperative association so requests, a total amount equal to not less than the sum of the individual payments otherwise payable to such producers under paragraphs (1) and (2) of this paragraph.

(b) On or before the last day of each month, each handler shall make an advance payment for milk purchased or received from producers during the first 15 days of the month to each producer at not less than $4.00 per hundredweight without deductions: *Provided*, That with respect to producers whose milk was caused to be delivered to such handler by a cooperative association, which is authorized to collect payments for such milk, if the cooperative association so requests, the handler shall pay such cooperative association an amount equal to the sum of the individual payments otherwise payable to such producers in accordance with this paragraph: *And provided further*, That the advance payment provided by this paragraph shall not be made to a new producer subject to the provisions of § 943.91 (a).

§ 943.81 *Producer-butterfat differential.* In making payments pursuant to § 943.80, there shall be added to or subtracted from the uniform price for each one-tenth of 1 percent that the average butterfat content of the milk received from the producer is above or below 4.0 percent, an amount computed by multiplying by 1.2 the simple average as computed by the market administrator of the daily wholesale selling prices per pound (using the midpoint of any price range as one price) of Grade A (92-score) bulk creamery butter at Chicago as reported by the Department during the month, dividing the resulting sum by 10, and rounding to the nearest one-tenth of a cent.

§ 943.82 *Producer-settlement fund.* The market administrator shall establish and maintain a separate fund known

as the "producer-settlement fund," into which he shall deposit all payments made by handlers pursuant to §§ 943.61 (b), 943.83 and 943.85, and out of which he shall make all payments to handlers pursuant to §§ 943.84 and 943.85.

§ 943.83 *Payments to the producer-settlement fund.* On or before the 13th day after the end of the month during which the milk was received, each handler, including a cooperative association which is a handler, shall pay to the market administrator the amount, if any, by which the value of the milk received by such handler from producers as determined pursuant to § 943.70 is greater than the amount required to be paid producers by such handler pursuant to § 943.80.

§ 943.84 *Payments out of the producer-settlement fund.* On or before the 14th day after the end of the month during which the milk was received, the market administrator shall pay to each handler, including a cooperative association which is a handler, the amount, if any, by which the value of the milk received by such handler from producers during the month as determined pursuant to § 943.70 is less than the amount required to be paid producers by such handler pursuant to § 943.80: *Provided*, That if the balance in the producer-settlement fund is insufficient to make all payments pursuant to this paragraph, the market administrator shall reduce uniformly such payments and shall complete such payments as soon as the necessary funds are available. No handler who has not received the balance of such payment from the market administrator shall be considered in violation of § 943.80 if he reduces his payments to producers by not more than the amount of the reduction in payment from the producer-settlement fund. The handler shall complete such payments to producers not later than the date for making such payments next following after the receipt of the balance from the market administrator.

§ 943.85 *Adjustment of accounts.* Whenever audit by the market administrator of any handler's reports, books, records, or accounts discloses errors resulting in money due:

(1) The market administrator from such handler;

(2) Such handler from the market administrator; or,

(3) Any producer or cooperative association from such handler, the market administrator shall promptly notify such handler of any amount so due and payment thereof shall be made on or before the next date for making payments set forth in the provisions under which error occurred.

BASE RATING

§ 943.90 *Determination of monthly base.* For each month during which payments to producers are made pursuant to established bases, the monthly base of each producer shall be a quantity of milk calculated by the market administrator by multiplying the number of days in such month by the daily base of each producer which has been determined pursuant to the provisions of § 943.91.

§ 943.91 *Determination of daily base.* Effective February 1, 1951, through September 30, 1951, and for the same months of each succeeding year, the daily base of each producer shall be a quantity of milk calculated by the market administrator in the following manner: Divide the total pounds of milk sold or delivered during the next preceding months of October, November, December and January by the total number of days in this 4-month period. This quantity of milk shall be known as such producer's daily base: *Provided*, That the daily base of a new producer coming on the market after the beginning of the base setting period shall be determined by dividing the total pounds of milk sold or delivered to a handler during the base setting period by the total number of days such producer delivered to a handler during the base setting period: *Provided further*, That when such producer sells or delivers for 90 days or less, and 30 days or more, during the base setting period, the following percentages shall be deducted from that producer's daily base:

Days:	*Deductions (percent)*
61 to 90	20
31 to 60	30

And provided further, That if a new producer sells or delivers milk to a handler for less than 30 days during the base setting period, he shall be allocated a temporary base in accordance with provisions of paragraph (a) of this section.

(a) A new producer who comes on the market after the base setting period has ended or less than 30 days before the end of such period shall be paid Class II price for all milk sold and delivered during the first fractional part of any month he is on the market and shall thereafter be allocated a temporary base computed by the market administrator, for use until the beginning of the base setting period, as follows: Divide the total pounds of milk sold or delivered to a handler during each full month thereafter until the beginning of the next base setting period by the number of days in that month, and subtract from that figure the following percentages for the applicable months:

Months:	*Percentages*	Months:	*Percentages*
January	30	June	70
February	40	July	70
March	50	August	60
April	50	September	50
May	60		

§ 943.92 *Base rules.* (a) Any producer who ceases to deliver milk to a handler for a period of more than 30 consecutive days, except as provided for in paragraph (e) of this section, shall forfeit his base. In the event such producer thereafter commences to deliver milk to a handler, he shall be allotted a daily base computed in the manner provided in § 943.91.

(b) A landlord who rents on a share basis shall be entitled to the entire daily base to the exclusion of the tenant if the landlord owns the entire herd. A tenant who rents on a share basis shall be entitled to the entire daily base to the exclusion of the landlord if the tenant owns the entire herd. If the cattle are jointly owned by the tenant and the landlord, the daily base shall be terminated when such share basis is terminated.

(c) A producer, whether a landlord or a tenant, may retain his base when moving his entire herd of cows from one farm to another.

(d) Base may not be transferred except (1) in case of the death (or retirement) of a producer, in which case his base may be transferred to a surviving member or members of his family who carry on the same dairy operation; and, (2) in case a producer goes out of the business of producing milk and sells 100 percent of his dairy herd, in which case the entire base may be transferred to the purchaser.

(e) For the purposes of this section only, the term "producer" shall include any person who has been a producer as defined in § 943.10 but whom the appropriate health officer or his authorized representative has suspended temporarily for failure to produce milk in conformity with the applicable health regulations.

MARKETING SERVICES

§ 943.100 *Marketing services.* (a) Except as set forth in paragraph (b) of this section, each handler, in making payments to producers (other than himself) pursuant to § 943.80, shall deduct 5 cents per hundredweight or such amount not exceeding 5 cents per hundredweight as may be prescribed by the Secretary, and shall pay such deductions to the market administrator on or before the 15th day after the end of each month. Such moneys shall be used by the market administrator to sample, test, and check the weights of milk received and to provide producers with market information.

(b) In the case of producers for whom a cooperative association is actually performing the services set forth in paragraph (a) of this section, each handler shall make, in lieu of the deduction specified in paragraph (a) of this section, such deductions from the payments to be made to such producers as may be authorized by the membership agreement or marketing contract between such cooperative association and such producers on or before the 15th day after the end of each month pay such deduction to the cooperative association rendering such services.

EXPENSES OF ADMINISTRATION

§ 943.110 *Expenses of administration.* As his pro rata share of the expense of administration hereof, each handler shall pay to the market administrator on or before the 15th day after the end of the month, 4 cents per hundredweight, or such amount not exceeding 4 cents per hundredweight as the Secretary may prescribe, with respect to all receipts within the month of (a) other source milk which is classified as Class I milk, and (b) milk from producers including such handler's own production.

TERMINATION OF OBLIGATION

§ 943.120 *Termination of obligation.* The provisions of this section shall apply to any obligation under this order for the payment of money.

(a) The obligation of any handler to pay money required to be paid under the terms in paragraphs (b) and (c) of this section, terminate two years after the last day of the calendar month during which the market administrator receives the handler's utilization report on the milk involved in such obligation, unless within such two-year period the market administrator notifies the handler in writing that such money is due and payable. Service of such notice shall be complete upon mailing to the handler's last known address, and it shall contain but need not be limited to, the following information:

(1) The amount of the obligation;

(2) The month(s) during which the milk, with respect to which the obligation exists, was received or handled; and,

(3) If the obligation is payable to one or more producers or to an association of producers, the name of such producer(s) or association of producers, or if the obligation is payable to the market administrator, the account for which it is to be paid.

(b) If a handler fails or refuses, with respect to any obligation under this order, to make available to the market administrator or his representatives all books and records required by this order to be made available, the market administrator may, within the two-year period provided for in paragraph (a) of this section, notify the handler in writing of such failure or refusal. If the market administrator so notifies a handler, the said two-year period with respect to such obligation shall not begin to run until the first day of the calendar month following the month during which all such books and records pertaining to such obligation are made available to the market administrator or his representatives.

(c) Notwithstanding the provisions of paragraphs (a) and (b) of this section, a handler's obligation under this order to pay money shall not be terminated with respect to any transaction involving fraud or willful concealment of a fact material to the obligation, on the part of the handler against whom the obligation is sought to be imposed.

(d) Any obligation on the part of the market administrator to pay a handler any money which such handler claims to be due him under the terms of this order shall terminate two years after the end of the calendar month during which the milk involved in the claim was received if an underpayment is claimed, or two years after the end of the calendar month during which the payment (including deduction or set-off by the market administrator) was made by the handler if a refund on such payment is claimed, unless such handler, within the applicable period of time, files, pursuant to section 8 (c) (15) (A) of the act, a petition claiming such money.

EFFECTIVE TIME, SUSPENSION OR TERMINATION

§ 943.130 *Effective time.* The provisions of this part or any amendment to this part shall become effective at such time as the Secretary may declare and shall continue in force until suspended or terminated pursuant to paragraph (b) of this section.

§ 943.131 *Suspension or termination.* The Secretary may suspend or terminate this part or any provision of this part whenever he finds this part or any provision of this part obstructs or does not tend to effectuate the declared policy of the act. This part shall terminate in any event whenever the provisions of the act authorizing it cease to be in effect.

§ 943.132 *Actions after suspension or termination.* If, upon the suspension or termination of any or all provisions of this part, there are any obligations thereunder, the final accrual or ascertainment of which requires further acts by any person (including the market administrator), such further acts shall be performed notwithstanding such suspension or termination.

§ 943.133 *Liquidation.* Upon the suspension or termination of the provisions of this part, except this section, the market administrator, or such other liquidating agent as the Secretary may designate, shall, if so directed by the Secretary, liquidate the business of the market administrator's office, dispose of all property in his possession or control, including accounts receivable, and execute and deliver all assignments or other instruments necessary or appropriate to effectuate any such disposition. If a liquidating agent is so designated, all assets, books and records of the market administrator shall be transferred promptly to such liquidating agent. If, upon such litigation, the funds on hand exceed the amounts required to pay outstanding obligations of the office of the market administrator and to pay necessary expenses of liquidation and distribution, such excess shall be distributed to contributing handlers and producers in an equitable manner.

MISCELLANEOUS PROVISIONS

§ 943.140 *Agents.* The Secretary may, by designation in writing, name any officer or employee of the United States to act as his agent or representative in connection with any of the provisions of this part.

§ 943.141 *Separability of provisions.* If any provision of this part or its application to any person or circumstances, is held invalid, the application of such provision and the remaining provisions of this part to other persons or circumstances, shall not be affected thereby.

The following proposals are modifications of the marketing area proposed to be defined in § 943.6 of the proposal of the North Texas Producers Association, Inc.:

Proposed by Wichita Falls Area Milk Producers Association, Inc.:

1. That the city limits of Wichita Falls, Texas, be included in the marketing area.

Proposed by Lamar Creamery Company, Paris, Tex.:

2. That the counties of Red River, Bowie, and Franklin, all in the State of Texas, and the counties of Choctaw, McCurtain, Pushmataha, and Bryan, all in the State of Oklahoma, be included in the marketing area.

Proposed by Boswell Dairies, Fort Worth, Tex.:

3. That the geographical area be changed and expanded to include all the territory in the following counties in their entirety: Tarrant, Dallas, Johnson, Palo Pinto, Parker, Erath, Wise, Hood, Hill, Jack, Ellis, and Denton Counties, all in the State of Texas.

Proposed by Vandervoorts, Inc., Fort Worth, Tex.:

4. That the following counties (all in the State of Texas) be included in the marketing area: Tarrant, Parker, Johnson, Erath, Comanche, Palo Pinto, Wise, Wichita, Denton, Dallas, Collin, Hood, Somervell, Ellis, Kaufman, Rockwall, Cooke, Grayson, Smith, and Gregg.

Proposed by Carnation Company of Texas, Chapman Dairy, and Coble's Dairyland, Wichita Falls, Tex.:

5. That there be included within the marketing area the entire counties of: Wichita, Wilbarger, Hardeman, Childress, Cottle, Foard, Knox, Haskell, Throckmorton, Shackelford, Jones, Baylor, Archer, Young, Stephens, Jack, Clay, Montague, all in the State of Texas.

Proposed by Tennessee Dairies, Dallas, Tex.:

6. All territory in the State of Texas, included within the area bounded on the north by the Red River and the State of Oklahoma, bounded on the east by and including the counties of Lamar, Delta, Hopkins, Wood, Upshur, Gregg, and Smith; bounded on the south by and including the counties of Smith, Van Zandt, Kaufman, Navarro, Ellis, Johnson, Parker, and Palo Pinto; and bounded on the west by and including the counties of Palo Pinto, Jack and Clay; and in addition all territory within the limits of the towns and cities of Abilene, Breckenridge, Sweetwater, Big Spring, Lubbock, Midland, Odessa, Pecos, San Angelo, Colorado City, Stephenville, Cisco, and Ranger, all in the State of Texas.

Proposed by Foremost Dairies, Inc., Fort Worth, Texas:

7. § 943.6. *North Texas marketing area.* "North Texas marketing area", hereinafter called the marketing area, shall include the following counties: Jack, Wise, Denton, Collin, Dallas, Ellis, Tarrant, Hood, Somervell, Erath, Palo Pinto, Johnson, Hill, Parker, Grayson, Cooke, Rockwell, Kaufman, Lamar, and Wichita, all in the state of Texas.

Copies of this notice of hearing may be procured from the Director, Dairy Branch, Production and Marketing Administration, United States Department of Agriculture, Washington 25, D. C., or from the Hearing Clerk, Room 1353, South Building, United States Department of Agriculture, Washington 25, D. C., or may be there inspected.

Dated: December 26, 1950, Washington, D. C.

[SEAL] ROY W. LENNARTSON,
Acting Assistant Administrator.

[F. R. Doc. 50-12581; Filed, Dec. 29, 1950; 8:58 a. m.]

[7 CFR, Parts 944, 970]

[AMA Docket No. AO-105-A7, Quad Cities]

[AMA Docket No. AO-174-A4, Clinton, Iowa]

HANDLING OF MILK IN QUAD CITIES AND CLINTON, IOWA, MILK MARKETING AREAS

NOTICE OF HEARING ON PROPOSED AMENDMENTS TO TENTATIVE MARKETING AGREEMENTS AND TO ORDERS, AS AMENDED

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.) and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), notice is hereby given of a joint public hearing to be held in the Council Chambers, Rock Island City Hall, Rock Island, Illinois, beginning at 10:00 a. m., c. s. t., January 3, 1951, for the purpose of receiving evidence with respect to economic and emergency conditions in each of the marketing areas specified above which relate to the proposed amendments hereinafter set forth, or appropriate modifications thereof, to the tentative marketing agreements heretofore approved by the Secretary of Agriculture and to the orders, as amended, now in effect, regulating the handling of milk in such marketing areas. These proposed amendments have not received the approval of the Secretary of Agriculture.

Proposed by the Illinois-Iowa Milk Producers Association and Quality Milk Association:

Proposal No. 1 (Quad Cities order). Amend § 944.5 (a) (1) and (2) to establish differentials for the months of January through June 1951, over the price for Class III milk for the previous delivery period as follows:

Class	Delivery Period	Grade A milk	Non-grade A milk
I	January, February, March	$1.15	$0.80
II	do	1.00	.65
I	April, May, June	.95	.60
II	do	.80	.45

Proposed by Clinton Cooperative Milk Association:

Proposal No. 2 (Clinton, Iowa order). Amend § 970.4 (a) (1) to establish differentials for the months of January through June 1951, over the price for Class II milk for the previous delivery period as follows:

Delivery period:	*Differentials*
January, February, March	$1.15
April, May, June	.95

Proposed by the Dairy Branch, Production and Marketing Administration:

Proposal No. 3. Make such other changes as may be required to make each of the marketing agreements and orders conform in their entirety with any amendments to such respective orders as may result from this hearing.

Copies of this notice of hearing, and the said orders, as amended, now in effect, may be procured from the Market Administrator, 335 Federal Building, 16th Street and 2d Avenue, Rock Island, Illinois, or from the Hearing Clerk, Room 1353, South Building, United States Department of Agriculture, Washington 25, D. C., or may be there inspected.

Dated: December 26, 1950, at Washington, D. C.

[SEAL] ROY W. LENNARTSON,
Acting Assistant Administrator.

[F. R. Doc. 50-12580; Filed, Dec. 29, 1950; 8:58 a. m.]

NOTICES

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[Order 2509, Amdt. 13]

SOLICITOR OF DEPARTMENT OF INTERIOR

DELEGATIONS OF AUTHORITY WITH RESPECT TO LIQUIDATED DAMAGES

Section 27 of Order No. 2509, as amended (15 F. R. 2785), is further amended to read as follows:

SEC. 27. *Liquidated damages.* If the Solicitor of the Department of the Interior determines that, as a matter of justice and equity, all or any part of the liquidated damages assessed on or after July 1, 1949, because of delay against a party to a contract made by the Department of the Interior or one of its agencies on behalf of the Government should be remitted, he is authorized to recommend to the Comptroller General that such a remission be made.

(Sec. 10, Pub. Law 754, 81st Cong., 2d Sess.; sec. 2, Reorg. Plan No. 3 of 1950, 15 F. R. 3174)

OSCAR L. CHAPMAN,
Secretary of the Interior.

DECEMBER 18, 1950.

[F. R. Doc. 50-12481; Filed, Dec. 29, 1950; 8:47 a. m.]

[Order 2591, Amdt. 1]

PETROLEUM ADMINISTRATION FOR DEFENSE

1. Paragraph (a) of section 2 of Order No. 2591 is amended by striking out the last three sentences of the paragraph and by inserting the following sentence in lieu thereof: "The Deputy Administrator shall report and be responsible directly to the Secretary of the Interior."

2. Paragraph (c) of section 2 of Order No. 2591 is amended by striking out the phrase "without the approval of the Administrator" and by inserting in lieu thereof the phrase "without the approval of the Secretary of the Interior".

OSCAR L. CHAPMAN,
Secretary of the Interior.

DECEMBER 21, 1950.

[F. R. Doc. 50-12482; Filed, Dec. 29, 1950; 8:47 a. m.]

DEPARTMENT OF AGRICULTURE

Production and Marketing Administration

MOORE & WOODS STOCKYARD

DEPOSTING AS A STOCKYARD

It has been ascertained that the Moore & Woods Stockyard, Tupelo, Mississippi, originally posted on September 21, 1938, as being subject to the Packers and Stockyards Act, 1921, as amended (7 U. S. C. 181 et seq.), no longer comes within the definition of a stockyard under said act for the reason that it no longer meets the area requirements. Therefore, notice is given to the owner of such stockyard and to the public that such stockyard is no longer subject to the provisions of said act.

Notice of public rule making has not preceded promulgation of the foregoing rule since it is found that the giving of such notice would prevent the due and timely administration of the Packers and Stockyards Act and would, therefore, be impractical. There is no legal warrant or justification for not depositing promptly a stockyard which no longer meets the area requirements of the act and is, therefore, no longer a stockyard within the definition contained in said act.

The foregoing rule is in the nature of a rule granting an exemption or relieving a restriction and, therefore, may be made effective in less than 30 days after publication thereof in the FEDERAL REGISTER. This notice shall become effective upon publication in the FEDERAL REGISTER.

(7 U. S. C. 181 et seq.)

Done at Washington, D. C., this 27th day of December 1950.

H. E. REED,
Director, Livestock Branch, Production and Marketing Administration.

[F. R. Doc. 50-12578; Filed, Dec. 29, 1950; 8:58 a. m.]

DEPARTMENT OF COMMERCE

Federal Maritime Board

NOTICE OF ESTABLISHMENT OF NEW DOCKETS

Notice is hereby given (1) that a docket has been established for applications for subsidies under the Merchant Marine Act, 1936, as amended, and all other proceedings related thereto, involving public hearings and reports by the Board or its predecessor, United States Maritime Commission, the docket symbol therefor to be the letter "S", followed by the number of the proceeding; and

(2) that a docket has been established for non-regulatory proceedings other than those above described, embracing miscellaneous matters involving public hearings and reports by the Board or its said predecessor, the docket symbol therefor to be the letter "M", followed by the number of the proceeding. Reports issued in connection with the above proceedings will be included in Volume 3 and succeeding volumes of the Board's printed reports. The new dockets herein referred to will be in addition to the docket now maintained for regulatory proceedings under the various shipping acts, the latest number of which is Docket No. 707.

In accordance with the foregoing paragraph, the following proceedings, including some which have not been reported as yet by the Board, have been assigned the docket symbols and numbers shown:

S-1: In the Matter of Applications for Operating-Differential Subsidy—American South African Line, Inc., Seas Shipping Company, Inc. Report dated August 5, 1938.

S-2 (Formerly No. 486): In re Application of the Baltimore Mail Steamship Company to Transfer Certain Vessels owned by it to Intercoastal Trade. Report dated June 7, 1938.

S-3 (Formerly No. 486): In re (1) Application of the Baltimore Mail Steamship Company for Amendment of the Order of June 7, 1938 Relating to Transfer of Certain Vessels Owned by it to Intercoastal Trade; (2) Application of Matson Navigation Company for Written Permission to Charter a Vessel Owned by it for Operation by the Baltimore Mail Steamship Company in Intercoastal Trade; and (3) Application of United States Lines Company and Baltimore Mail Steamship Company for Permission to Charter the S. S. *Washington* for Operation by the Baltimore Mail Steamship Company in a Single Voyage in Intercoastal Trade. Report dated December 9, 1938.

S-4. In the Matter of Applications of Bloomfield Steamship Company and Lykes Bros. Steamship Co., Inc., for Financial Aid under Title VI of the Merchant Marine Act, 1936, as amended, in the Operation of Vessels on Trade Route No. 15 B (United States Gulf to South and East African Ports). Report dated November 8, 1946.

S-5: In the Matter of Application of the Oceanic Steamship Company for Financial Aid Under Title VI of the Merchant Marine Act of 1936, as amended, in the Operation of Vessels on Freight Services a and b Trade Route No. 27 (U. S. Pacific Ports—Australia, New Zealand, New Guinea and South Sea Islands). Report dated December 30, 1946.

S-6: In the Matter of Applications of American South African Line, Inc., Mississippi Shipping Company, Inc., and Seas Shipping Company, Inc. for Financial Aid Under Title VI of the Merchant Marine Act, 1936, as amended, in the Operation of Vessels on Trade Route No. 14 (United States Atlantic and Gulf Ports and West Coast of Africa). Report dated January 9, 1947.

S-7: In the Matter of Applications of United States Lines Company, American President Lines, Ltd., American Export Lines, Inc., Lykes Bros. Steamship Co., Inc., American-Hawaiian Steamship Company, American Mail Line, Ltd., Olympic Steamship Company, and States Steamship Company for Financial Aid Under Title VI of the Merchant Marine Act, 1936, as amended, in the Operation of Vessels on Essential Foreign Trade Routes Nos. 12, 17, 22, 28, 29, and 30, as described in Report of the Commission, approved May 20, 1946, and application of Grace Line Inc. for Permission to Operate on Freight Service "F" of Trade Route No. 29, Without Subsidy. Report dated June 9, 1947.

S-8: In the Matter of Minimum Wage, Minimum Manning and Reasonable Working Conditions on Subsidized Vessels.

S-9: Application of Lykes Bros. Steamship Company, Inc., Under Section 805 (a), Merchant Marine Act, 1936, as amended—Emergency Intercoastal Operation. Report dated November 25, 1947.

S-10: Applications of Arnold Bernstein Steamship Corporation, Black Diamond Steamship Corporation, United States Lines Company, and South Atlantic Steamship Line, Inc., for Financial Aid Under Title VI of the Merchant Marine Act, 1936, as amended, in the Operation of Vessels on Essential Foreign Trade Routes Nos. 7-8—U. S. North Atlantic Ports—Antwerp, Hamburg Range et al.; and Trade Routes No. 11—U. S. South Atlantic Ports—United Kingdom and Eire, Continental Europe, Scandinavian and Baltic Ports, as Described in Report to the Commission dated May 20, 1946. Order dated February 18, 1948.

S-11: In the Matter of the Application of American President Lines, Ltd., to Operate, Without Subsidy, Service C-2 of Trade Route No. 17. Resolution dated May 18, 1948.

S-12: In the Matter of Pacific Argentine Brazil Line, Inc.—Application for Operating-Differential Subsidy (Trade Route 24) Under Title VI, Merchant Marine Act, 1936. Report dated November 5, 1948.

S-13: In the Matter of Arnold Bernstein Line, Inc.—Application for Operating-Differential Subsidy for Operation of a Passenger and Cargo Service on Trade Route No. 8, Under Title VI, Merchant Marine Act, 1936. Report dated March 21, 1949.

S-14: In the Matter of Shepard Steamship Co.—Application for Operating-Differential Subsidy (Trade Route No. 1) Under Title VI, Merchant Marine Act, 1936. Report dated March 21, 1949.

S-15: Moore-McCormack Lines, Inc.—Resumption of Operating-Differential Subsidy for "Good Neighbor Fleet." Report dated April 13, 1950.

S-16: Pacific Argentine Brazil Line, Inc.—Application under Section 805 (a) of the Merchant Marine Act, 1936, as amended, for Permission for its Parent Company, Pope & Talbot, Inc., to Engage in Pacific Coastwise Trade. Report dated May 18, 1950.

S-17: In the matter of the Application of American President Lines, Ltd., to Continue Operation after December 31, 1949, of Atlantic-Straits Freight Service C-2, Trade Route No. 17, Without Operating-Differential Subsidy.

S-18: In the Matter of Pacific Transport Lines, Inc.—Application for Operating-Differential Subsidy, Trade Route 29, Service 2.

S-19: In the Matter of Pacific Far East Line, Inc.—Application for Operating-Differential Subsidy, Trade Route 29, Service 2.

S-20: In the Matter of American President Lines, Ltd.—Application for Permission to Operate Vessels Between California Ports and Guam, Midway and Wake Under Section 805 (a) of Merchant Marine Act, 1936.

S-21: In the Matter of United States Lines Company—Application for Operating-Differential Subsidy, Trade Route No. 8, Service 2, Under Title VI, Merchant Marine Act, 1936.

M-1: The Florida National Bank of Jacksonville—Application for Commitment to Insure a Preferred Ship Mortgage.

M-2: American-Hawaiian Steamship Company and Pittsburgh Steamship Company—Applications for Extension of Period for Commitment of Construction Reserve Fund Deposits under Section 511 of the Merchant Marine Act, 1936, as amended. Report dated November 30, 1949.

M-3: American Mail Line, Ltd., Pacific Transport Lines, Inc., Pacific Atlantic S. S. Co., Pacific Far East Line, Inc., American President Lines, Ltd., and States Marine Corporation—Applications for Bareboat Charter of Dry-Cargo Vessels for Use in Trans-Pacific Service. Report dated July 14, 1950.

M-4: In the Matter of Pope & Talbot, Inc.—Application for Bareboat Charter of War-Built Dry-Cargo Vessels for Use in the Intercoastal Trade. Report dated July 20, 1950.

M-5: In the Matter of Coastwise Line—Application for Bareboat Charter of War-Built Dry-Cargo Vessels for Use in the Alaska Trade. Report dated July 26, 1950.

M-6: In the Matter of Actium Shipping Corp., et al.—Applications for Bareboat Charter of War-Built Dry-Cargo Vessels for Use in the Trans-Pacific Area Under Time Charter to Military Sea Transportation Service of the Department of the Navy. Reports dated July 27, 1950, and August 1, 1950.

M-7: In the Matter of Actium Shipping Corp., et al.—Applications for Bareboat Charter of War-Built Dry-Cargo Vessels for Use in the Trans-Pacific Area Under Time Charter to Military Sea Transportation Service of the Department of the Navy. Report dated August 4, 1950.

M-8: In the Matter of Actium Shipping Corp., et al.—Applications for Bareboat Charter of War-Built Dry-Cargo Vessels for Use in the Trans-Pacific Area Under Time Charter to Military Sea Transportation Service of the Department of the Navy. Report dated August 17, 1950.

M-9: Grace Line, Inc.—Application for Extension of Bareboat Charter Agreement beyond October 31, 1950, for War-Built Dry-Cargo Vessels, Under Section 5 of the Merchant Ship Sales Act of 1946, as amended by Public Law 591, 81st Congress. Report dated September 26, 1950.

M-10: Pacific Far East Line, Inc.—Application for Extension of Bareboat Charter Agreement Beyond October 31, 1950, for Fully Refrigerated War-Built Dry-Cargo Vessels, Under Section 5 of the Merchant Ship Sales Act of 1946, as amended by Public Law 591, 81st Congress. Report dated September 26, 1950.

M-11: In the Matter of the Application of Alaska Steamship Company for Bareboat Charter Extension with Permission to Time Charter to Grace Line, Inc., and of Coastwise Line for Bareboat Charter Extension. Report dated October 17, 1950.

M-12: In the Matter of Pope & Talbot, Inc.—Application for Bareboat Charter of War-Built Dry-Cargo Vessels for Use in the Intercoastal Trade. Report dated October 17, 1950.

M-13: In the Matter of the Applications of American-Hawaiian Steamship Company, Luckenbach Steamship Company, Inc., Pacific-Atlantic Steamship Co., and Pope & Talbot Inc., for Extension of Bareboat Charter Agreements of Government-Owned, War-Built, Dry-Cargo Vessels in the Intercoastal Trade. Report dated October 17, 1950.

M-14: In the Matter of the Applications of American-Hawaiian Steamship Company and Luckenbach Steamship Company, Inc., to Bareboat Charter Government-owned War-Built Dry-Cargo Vessels.

M-15: In the Matter of American Export Lines, Inc., et al.—Applications for Bareboat Charter of War-Built, Dry-Cargo Vessels for Use in the Carriage of Coal and Grain from the United States to European Countries. Report dated December 20, 1950.

FEDERAL MARITIME BOARD,
[SEAL] A. J. WILLIAMS,
Secretary.

DECEMBER 26, 1950.

[F. R. Doc. 50-12518; Filed, Dec. 29, 1950; 8:52 a. m.]

Office of International Trade

[Case No. 95]

CARL LOHMAN JANIK

ORDER REVOKING AND DENYING LICENSE PRIVILEGES

In the matter of Carl Lohman Janik, 9 Rockefeller Plaza, New York 20, N. Y., respondent.

This proceeding was begun by the issuance of a charging letter dated September 8, 1950, wherein the Office of Industry and Commerce charged the respondent with having violated section 6 of the act of July 2, 1940 (54 Stat. 714), as amended, and the Export Control Act of 1949 (63 Stat. 7), and the regulations promulgated under said statutes. During the period between June 1 and October 11, 1950, said Office of Industry and Commerce administered export controls within the Department of Commerce. Prior to and since that period, export controls were and are now administered by the Office of International Trade in the Department of Commerce.

It was alleged in said charging letter that the respondent had made certain shipments and transshipments of machinery and electronic equipment to Czechoslovakia without the required export licenses or contrary to the terms of licenses which he held. The first charge described in the charging letter was that on or about May 28, 1948, the respondent shipped an electronic tube-manufacturing device known as a button-stem machine, together with 250 kilograms of mold metal, to Czechoslovakia without having any validated outstanding license in his possession which permitted such exportation, and by the use of a license which had previously, to his knowledge, been officially suspended by the Office of International Trade. The second charge was that, in the spring of 1949, the respondent shipped a signal generator, an oscilloscope, and two frequency meters to Italy, under a validated license authorizing such exportation, and ostensibly for display at an Italian trade fair, which electronic equipment respondent intentionally caused to be transshipped to Czechoslovakia through an Italian intermediary. The third charge was that in March 1949, respondent shipped 85 radio tubes and sockets to Czechoslovakia through the mails, through misdescription of the shipment and in violation of the general license regulations of the Office of International Trade then in effect. The fourth charge was that in February 1949, respondent exported 32 diamond dies to Czechoslovakia by inducing a returning Czech to carry the dies in his baggage, without compliance with, and contrary to, the export control law and regulations. The fifth charge was that between March 1948 and the date of the charging letter, respondent made other miscellaneous exports to Czechoslovakia without compliance with the export license regulations, through the subterfuges of undervaluation or the splitting of shipments into several parts.

Prior to the issuance of the charging letter, the Office of Industry and Commerce issued a temporary suspension order under date of July 12, 1950, against the respondent, on the application of its Enforcement Section, the effect of which order was to bar respondent from making any export shipments under either validated or general license pending the completion of the investigation being conducted by the Enforcement Section. Following service of the temporary suspension order, the respondent moved to set it aside and requested an oral hearing on his motion, which hearing was held in Washington, D. C., on August 10, 1950, before the Compliance Commissioner. Respondent was represented by counsel, testified at considerable length, and submitted oral and documentary evidence to show mitigating reasons for the acts charged. Evidence to show the existence of reasonable ground for the temporary suspension order was introduced on behalf of the Enforcement Section. At the conclusion of the hearing, the Compliance Commissioner recommended continuance of the suspension order in effect. Thereafter, the temporary suspension order was extended on August 28, 1950, and again on September 11, 1950, the latter extension having been granted on the basis of the issuance of the charging letter, and providing that the suspension order remain in effect until final disposition of the administrative compliance proceeding instituted by the charging letter.

Prior to the hearing on respondent's motion to set aside the temporary suspension order, the respondent filed a document wherein he substantially admitted the first two charges described above and pleaded that his violations were justified by an objective which he described as patriotic and of ultimate benefit to the United States. After the issuance of the charging letter, no further hearing was requested by the respondent, his position being that the merits of his case had already been presented and that an additional hearing would serve no purpose. The respondent accordingly waived such further hearing, and the evidence in the case was therefore informally presented to the Compliance Commissioner by the Enforcement Section. In addition, counsel for Janik submitted a brief to the Compliance Commissioner in which it was again urged that Janik's violations were prompted by misguided but patriotic motives and that a further suspension would not be warranted.

The Compliance Commissioner has under date of November 22, 1950, prepared and filed with the Assistant Director for Export Supply, Office of International Trade, his report on the case, including the evidentiary materials submitted by the respondent and the Enforcement Section, and the brief filed by counsel for the respondent, together with the Commissioner's findings and recommendations thereon.

It appears from the record and the Compliance Commissioner's report that the first four charges described above have all been either openly admitted or not contested by the respondent. With respect to the fifth charge of miscellaneous shipments, the Commissioner has reported that, although he found some evidence of other minor shipments having been made without license through the subterfuges of undervaluation or splitting shipments into several parts, and evidence that the respondent tried and perhaps succeeded in some instances in making arrangements for transshipments to Czechoslovakia through countries other than Italy, the Compliance Commissioner did not find such clear and convincing evidence of specific violations as to warrant a finding that the fifth charge had been substantiated in any particular instance.

It further appears from the record and the Compliance Commissioner's report that the respondent has not denied making the shipments charged or that he knew he was violating the export control regulations when he made them, and that his defense has been only that he was consciously violating the export control law for what he deemed to be a justifiable and laudable purpose. It further appears from the record and the report of the Compliance Commissioner, however, that respondent has, prior to and in the course of this proceeding, made such inconsistent statements as to cast serious doubt upon both his credibility and his future trustworthiness in the export business.

The Compliance Commissioner has therefore recommended that the respondent be denied export license privileges for the duration of export controls in respect of the use of validated licenses or the shipment of positive list commodities either under validated or general licenses, but that his privilege of making shipments of other than positive list commodities under general license be not denied.

The Assistant Director for Export Supply has carefully considered the report of the Compliance Commissioner, together with the record in this case and the oral argument and brief presented to him by respondent's counsel. It appears that the findings of the Compliance Commissioner, as set forth in his report, are supported by the record and that, with one exception, his recommendations are fair and reasonable and should be adopted. It is the considered judgment of the Assistant Director for Export Supply that because respondent has in the past admittedly abused his general license privileges, there is a serious hazard that he may in the future again employ general license privileges to attempt to export positive list commodities under the guise of general license commodities. Accordingly, having in mind this element of the case and the very serious nature of the case as a whole, the Assistant Director for Export Supply has concluded that the recommendation of the Compliance Commissioner that the respondent's privilege of making shipments of non-positive list commodities under general license be not suspended, should not be adopted in this order, and that, instead, respondent should be generally denied the privilege of making any exportation of any commodity from the United States under validated or general license to any destination so long as export controls may be and remain in effect. Now, therefore, it is ordered as follows:

(1) All outstanding export licenses in which respondent appears as licensee, consignor, forwarder, intermediate con-

signee, ultimate consignee, or otherwise as a party in any capacity, are hereby revoked and shall be forthwith returned to the Office of International Trade for cancellation.

(2) Respondent is hereby denied for the duration of export control the privilege of obtaining or using or participating directly or indirectly either as licensee, consignor, forwarder, intermediate consignee, ultimate consignee, or otherwise in any capacity as a party in the obtaining or using of export licenses, including general licenses, as well as validated licenses, for shipment from the United States to any destination of any commodity.

(3) Such revocation and denial shall extend not only to the respondent, but also to any other person, trade name, firm, corporation, or other business association with which respondent may be now or hereafter related by ownership control, or a position of responsibility involving the preparation, filing, procurement, or use of any export control documents, or the supervision of any person so engaged in the conduct of export trade.

Dated: December 26, 1950.

JOHN C. BORTON,
Assistant Director for Export Supply.

[F. R. Doc. 50-12408; Filed, Dec. 29, 1950; 8:45 a. m.]

FEDERAL COMMUNICATIONS COMMISSION

PUBLIC SAFETY AND AMATEUR DIVISION

ORDER AMENDING ORDER ESTABLISHING SAFETY AND SPECIAL RADIO SERVICE BUREAU

In the matter of amendment of the Commission's "Order Establishing Safety and Special Radio Services Bureau", to change the name of one of the divisions thereof to Public Safety and Amateur Division.

At a session of the Federal Communications Commission held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration its "Order Establishing Safety and Special Radio Services Bureau", which became effective July 31, 1950,[1] and which established a new bureau called the Safety and Special Radio Services Bureau, comprised of five divisions, namely: Aviation Division, Marine Division, State-Local Government and Amateur Division, Industry and Commerce Division, and Authorization Analysis Division;

It appearing, that the name State-Local Government and Amateur Division was intended to be descriptive of the radio services administered, but that such appellation is somewhat misleading for the reason that many licensees in the particular radio services for which the division is specifically responsible in fact are not instrumentalities either of state or local government, and conversely some state and local governments are licensed in radio services not administered by the division;

It further appearing, that the name Public Safety and Amateur Division would better describe the functions of the division and be a more appropriate name;

It is ordered, This 13th day of December 1950, that the name State-Local Government and Amateur Division be and it hereby is changed to Public Safety and Amateur Division;

It is further ordered, That the Commission's Order Establishing Safety and Special Radio Services Bureau, insofar as it refers to the State-Local Government and Amateur Division, be and it hereby is amended by changing the name of that division to Public Safety and Amateur Division.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12406; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket Nos. 9779-9782]

MOBILE RADIO MESSAGE SERVICE ET AL.

ORDER DELETING ISSUES

In re applications for construction permits or licenses, respectively, in the Domestic Public Land Mobile Radio Service at Houston, Texas. Roberta B. Knigge and Joseph H. Wofford, d/b as Mobile Radio Message Service, Docket No. 9779, Files Nos. 3983/3984-C2-ML-E; W. M. Hollomon, d/b as Hollomon Radio Dispatch Service, Docket No. 9780, Files Nos. 4853/4854-C2-ML-E and 5668-C2-P-E; Robert E. Franklin, Docket No. 9781, File No. 4847-C2-P-E; O. B. English, d/b as English Radio Dispatch Co., Docket No. 9782, File No. 21553-C2-P-E.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission, having under consideration its order dated September 6, 1950, in the above entitled matter; and

It appearing, that the Commission, in its memorandum opinion and order in Docket No. 9648, dated October 18, 1950, has resolved the question set forth in issue No. 3 therein and that such issue is now moot; and

It further appearing, that it is desirable to amend issue No. 4 so that the facts and information to be obtained in connection therewith may be more definitely described; and to renumber the issues as may be appropriate;

It is ordered, That the Commission's order herein dated September 6, 1950, is amended by deletion of the issues therein set forth and substitution of the following issues to be determined in the proceeding:

1. To determine the legal, technical and financial qualifications of each of the above-entitled applicants to construct and operate the proposed stations.

2. To determine the areas which may be expected to receive service from the proposed stations and the need for such service in the areas proposed to be served.

3. To determine whether any mutual interference would result from operation of the proposed stations, and, if so, whether, in view of the nature of the service proposed, such interference would be undesirable or intolerable.

4. To determine the facts with respect to the existing and proposed facilities, personnel, rates, regulations, practices and services of each applicant for the furnishing of Domestic Public Land Mobile Radio Service.

5. To determine, in the light of the evidence on the foregoing issues, which applicants are best qualified to serve the public interest, convenience or necessity.

6. To determine, on a comparative basis, which, if any, of the applications in this consolidated proceeding should be granted.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12407; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket Nos. 9761-9769, 9771-9773]

TELEPHONE MESSAGE SERVICE OF YONKERS ET AL.

ORDER DELETING ISSUES

In re applications for construction permits or licenses, respectively, in the Domestic Public Land Mobile Radio Service of Telephone Message Service of Yonkers, Yonkers, New York, Docket No. 9761, Files Nos. 1316 and 1372-C2-ML-E; Harold W. Graf, Hempstead, New York, Docket No. 9762, Files Nos. 2040/2041-C2-ML-E; Harold W. Graf, Bay Shore, New York, Docket No. 9763, Files Nos. 1223/1224-C2-P-E; Telephone Secretarial Service, Inc., Newark, New Jersey, Docket No. 9764, Files Nos. 4855/4856-C2-ML-E; Peter T. Kroeger, d/b as Mobile Radio Dispatch Service, New Brunswick, New Jersey, Docket No. 9765, Files Nos. 3639/3640-C2-ML-E; J. J. Freke-Hayes, New York, New York, Docket No. 9766, Files Nos. 3041/3042-C2-ML-E; Solomon Schiller, Brooklyn, New York, Docket No. 9767, Files Nos. 2892/2893-C2-ML-E; Westchester Mobilfone System, Inc., Mt. Pleasant, New York, Docket No. 9768, Files Nos. 3534/3535-C2-ML-E; Huntington Radio Dispatch Service, tr/as Knights Packard Service, Huntington, New York, Docket No. 9769, File No. 18666-C2-P-E; James P. Rogers, d/b as Suburban Radiotelephone, West Orange, New Jersey, Docket No. 9771, File No. 5170-C2-P-E; Mildred Tarone, d/b as Doctors' Telephone Exchange and Huntington Telephone Answering Service, Huntington, New York, Docket No. 9772, Files Nos. 12015/12016-C2-P/L-E; Electro Craft, Inc., Stamford, Connecticut, Docket No. 9773, Files Nos. 4974/4975-C2-P-E.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission, having under consideration its order dated August 23, 1950, in the above entitled matter; and

[1] 15 F. R. 4381.

It appearing, that the Commission, in its memorandum opinion and order in Docket No. 9648, dated October 18, 1950, has resolved the question set forth in issue No. 4 therein and that such issue is now moot; and

It further appearing, that it is desirable to amend issue No. 5 so that the facts and information to be obtained in connection therewith may be more definitely described, and to renumber the issues as may be appropriate;

It is ordered, That the Commission's order herein dated August 23, 1950, is amended by deletion of the issues therein set forth and substitution of the following issues to be determined in the proceeding:

1. To determine the legal, technical, and financial qualifications of each of the above-entitled applicants to construct and operate the proposed stations.

2. To determine the areas and populations which may be expected to receive service from any proposed station and the need for such service in the area proposed to be served.

3. To determine whether co-channel operations are feasible between any of the communities involved in this proceeding.

4. To determine whether any mutual interference would result from operation of the proposed stations, and, if so, whether, in view of the nature of the service proposed, such interference would be undesirable or intolerable.

5. To determine the facts with respect to the existing and proposed facilities, personnel, rates, regulations, practices and services of each applicant for the furnishing of Domestic Public Land Mobile Radio Service.

6. To determine, in the light of the evidence on the foregoing issues, which applicants are best qualified to serve the public interest, convenience or necessity.

7. To determine, on a comparative basis, which, if any, of the applications in this consolidated proceeding, should be granted.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12498; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket Nos. 9723-9731]

ROBERT C. CRABB ET AL.

ORDER DELETING ISSUES

In re applications for construction permits or licenses, respectively, in the Domestic Public Land Mobile Radio Service of Robert C. Crabb, Los Angeles, California, Docket No. 9723, Files Nos. 4118/4119-C2-ML-E; Lyman G. Berg, d/b as American Telephone Answering Service, Physicians' Exchange, Radio Message Service and Television Answering Service, Signal Hill (Long Beach), California, Docket No. 9724, Files Nos. 3977/3978-C2-ML-E; W. T. German, d/b as United Radio Communications, San Diego, California, Docket No. 9725, Files Nos. 3538/3539-C2-ML-E; Art Parlas, d/b as Tri-City Radio Dispatch Company, San Bernardino, California, Docket No. 9726, Files Nos. 5003/5004-C2-ML-E; Business and Professional Telephone Exchange, Los Angeles and Pasadena, California, Docket No. 9727, Files Nos. 2036/2037-C2-L-E and 364-C2-P-E; Benjamin H. Warner & Vernon C. Starr, d/b as Orange County Radiotelephone Service, Santa Ana, California, Docket No. 9728, Files Nos. 3744/3745-C2-P-E; H. W. Ziegler & H. Paul Roman, d/b as Automotive Communications Company, Pomona, California, Docket No. 9729, Files Nos. 18646/18647-C2-P-D; Clyde Downen, Downey, California, Docket No. 9730, Files Nos. 23/24-C2-P-E; G. Earle Colee & Christine N. Colee, d/b as Telephone Answering Bureau, Santa Monica, California, Docket No. 9731, File No. 8099-C2-P-E.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C. on the 13th day of December 1950;

The Commission, having under consideration its order dated July 6, 1950, in the above entitled matter; and

It appearing, that the Commission, in its memorandum opinion and order in Docket No. 9648, dated October 18, 1950, has resolved the question set forth in issue No. 4 therein and that such issue is now moot; and

It further appearing, that it is desirable to amend issue No. 5 so that the facts and information to be obtained in connection therewith may be more definitely described; and to renumber the issues as may be appropriate;

It is ordered, That the Commission's order herein dated July 6, 1950, is amended by deletion of the issues therein set forth and substitution of the following issues to be determined in the proceeding:

1. To determine the legal, technical, and financial qualifications of each of the above-entitled applicants to construct and operate the proposed stations.

2. To determine the areas and populations which may be expected to receive service from any proposed station and the need for such service in the area proposed to be served.

3. To determine whether co-channel operations are feasible between any of the communities involved in this proceeding.

4. To determine whether any mutual interference would result from operation of the proposed stations, and, if so, whether, in view of the nature of the service proposed, such interference would be undesirable or intolerable.

5. To determine the facts with respect to the existing and proposed facilities, personnel, rates, regulations, practices and services of each applicant for the furnishing of Domestic Public Land Mobile Radio Service.

6. To determine, in the light of the evidence on the foregoing issues, which applicants are best qualified to serve the public interest, convenience or necessity.

7. To determine, on a comparative basis, which, if any, of the applications in this consolidated proceeding should be granted.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12499; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket No. 9858]

WEST COAST TELEPHONE CO. AND ITS CONNECTING AND CONCURRING CARRIERS

ORDER SCHEDULING HEARING

In the matter of charges, classifications, regulations and practices for and in connection with channels for program transmission of West Coast Telephone Company and its connecting and concurring carriers.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration new tariff schedules filed by the West Coast Telephone Company designated as its Tariff F. C. C. No. 12, to become effective December 20, 1950, in which certain increased charges and new charges for interstate channels for program transmission are proposed to be made; and also having under consideration revised tariff schedules filed by The Pacific Telephone and Telegraph Company also effective December 20, 1950, designated as follows:

Tariff F. C. C. No. 87

11th Revised Page 2.
8th Revised Page 3.
10th Revised Page 28-B.
5th Revised Page 28-C.
2d Revised Page 28-D.
4th Revised Page 28-E.
9th Revised Page 29.
9th Revised Page 30.
8th Revised Page 31.
8th Revised Page 32.
10th Revised Page 33.
15th Revised Page 34.
13th Revised Page 35-A.
2d Revised Page 35-C.
2d Revised Page 35-D.
1st Revised Page 35-E.
1st Revised Page 35-F.
1st Revised Page 35-G.

cancelling the schedules heretofore contained in its tariff applicable to interstate program transmission service furnished by West Coast Telephone Company and West Coast Telephone Company of California;

It appearing, that the Commission is unable to determine from an examination of the above mentioned tariff schedules issued by West Coast Telephone Company whether the charges, classifications, regulations and practices therein contained will be just and reasonable or otherwise lawful under the Communications Act of 1934, as amended.

It further appearing, that if such new and revised tariff schedules are permitted to become effective the rights and interests of the public may be adversely affected thereby;

It is ordered, That, pursuant to sections 201, 202, 204, 205 and 403 of the Communications Act of 1934, as amended, the Commission, upon its own motion and without formal pleading, shall enter upon a hearing and investigation concerning (1) the lawfulness of the charges, classifications, regulations and practices set forth in the above-cited new and revised tariff schedules, and (2) the lawfulness of the charges, classifications, regulations and practices provided for in the currently effective tariff schedules of the carriers named respondent herein, on file with this Commission, applicable to Channels for Program Transmission furnished by West Coast Telephone Company and West Coast Telephone Company of California;

It is further ordered, That, pursuant to section 204 of the Communications Act of 1934, as amended, the operation of the above-cited new tariff schedules issued by West Coast Telephone Company and revised tariff schedules issued by Pacific Telephone and Telegraph Company is hereby suspended until March 20, 1951, unless otherwise ordered by the Commission; and that during said period of suspension no changes shall be made in said tariff schedules, or in the charges, classifications, regulations or practices sought to be altered thereby, unless authorized by special permission of the Commission;

It is further ordered, That without in any way limiting the scope of the hearing and investigation herein, inquiry shall be made into the following specific matters:

(1) The lawfulness under sections 201 and 202 of the Communications Act of 1934, as amended, of the charges, classifications, regulations and practices set forth in the above-cited new and revised tariff schedules, as well as those set forth in the currently effective tariff schedules of the carriers named respondent herein, on file with this Commission and applicable to Channels for Program Transmission furnished by West Coast Telephone Company and West Coast Telephone Company of California;

(2) Whether, under section 205 (a) of the Communications Act of 1934, as amended, the Commission should prescribe just, fair and reasonable charges, classifications, regulations and practices for and in connection with the services covered by the above-cited tariff schedules, and, if so, what charges, classifications, regulations or practices should be so prescribed;

It is further ordered, That in the event a decision as to the lawfulness of the charges, classifications, regulations and practices herein suspended has not been made during the aforesaid suspension period, and said charges, classifications, regulations and practices set forth in the above-cited tariff schedules go into effect, West Coast Telephone Company and its connecting and concurring carriers shall, until further order of the Commission, keep accurate accounts of all amounts charged, collected or received by reason of the charges set forth in said tariff schedules, specifying by whom and in whose behalf such amounts are paid; and shall file with the Commission a report on or before the 10th day of each calendar month, commencing April 10, 1951, showing the amounts accounted for as aforesaid during the previous calendar month;

It is further ordered, That a copy of this order be filed in the offices of the Commission with said tariff schedules herein suspended; that West Coast Telephone Company and all carriers listed in its suspended tariff schedules as concurring and connecting carriers and The Pacific Telephone and Telegraph Company are hereby made parties respondent to this proceeding; and that a copy hereof be served on each such respondent;

It is further ordered, That hearings be held in this proceeding at the offices of the Commission in Washington, D. C., beginning at 10 a. m. on the 22d day of January 1951; that Elizabeth C. Smith is assigned to preside at such hearings; and that the presiding officer shall certify the record to the Commission for decision and shall not prepare either a recommended decision or initial decision.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12500; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket No. 9700]

SOUTHERN TIER RADIO SERVICE, INC. (WINR)

ORDER DELETING ISSUE AND SCHEDULING HEARING

In re application of Southern Tier Radio Service, Inc. (WINR), Binghamton, New York, for construction permit; Docket No. 9700, File No. BP-7619.

At a session of the Federal Communications Commission, held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration a petition filed on June 29, 1950 by Southern Tier Radio Service, Incorporated requesting reconsideration and grant without hearing of the above-entitled application for construction permit to change the facilities of Station WINR, Binghamton, New York, from frequency 1490 kilocycles, 250 watts power, unlimited time to frequency 680 kilocycles, 500 watts, 1 kilowatt-LS power, unlimited time, to install directional antenna (DA-2), to install new transmitter and to change transmitter location;

It appearing, that the said application was designated for hearing by Commission order of June 1, 1950 to determine among other matters whether the installation and operation of Station WINR, as proposed, would be in compliance with the Commission's rules and Standards of Good Engineering Practice concerning Standard Broadcast Stations with particular reference to the nighttime coverage of the Binghamton metropolitan area, and the areas and populations which will receive satisfactory service and to determine the overlap, if any, that will exist between the service areas of Station WINR operating as proposed and of Stations WSYR and WNDR and whether such overlap, if any, is in contravention of § 3.35 of the Commission's rules; and

It further appearing, that on the basis of the information contained in the said petition there does not appear to be a question of common ownership between Stations WINR and WNDR involved as contemplated under § 3.35 of the Commission's rules, but that the proposed operation of Station WINR may not provide satisfactory nighttime service to the Binghamton metropolitan district, that the proposed operation may receive daytime interference in excess of that recommended by the Standards of Good Engineering Practice, that population residing between the normally protected and interference free nighttime contours may be in excess of that recommended by the Standards of Good Engineering Practice and that overlap in contravention of § 3.35 of the Commission's rules may exist between the service areas of Station WINR operating as proposed and Station WSYR and accordingly, on the basis of the information contained in the said application and petition the Commission cannot determine whether a grant of the above-entitled application would be in the public interest;

It is ordered, That the said petition is denied and, on the Commission's own motion, issue 4 in the order of June 1, 1950 designating the said application for hearing is amended to delete therefrom all reference to Station WNDR, Syracuse, New York; and that the hearing in the above-entitled proceeding is scheduled to be heard at 10:00 a. m., Thursday, January 25, 1951, at Washington, D. C.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12501; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket No. 9859]

KEE BROADCASTING CO.

ORDER DESIGNATING APPLICATION FOR HEARING ON STATED ISSUES

In re application of E. D. Scandrett, Harold B. Rothrock and Ray F. Knochel d/b as Kee Broadcasting Company, Kewanee, Illinois, for construction permit; Docket No. 9859, File No. BP-7287.

At a session of the Federal Communications Commission held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration the above-entitled application requesting a permit to construct a new standard broadcast station to operate on frequency 1450 kilocycles, with 100 watts power, unlimited time at Kewanee, Illinois;

It appearing, that the applicant is legally, technically, financially and otherwise qualified to operate the proposed station, but that the application may involve interference with one or more

existing stations and otherwise not comply with the Standards of Good Engineering Practice;

It is ordered, That, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application is designated for hearing at 10:00 a. m. on February 1, 1951, at Washington, D. C., upon the following issues:

1. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed station, and the character of other broadcast service available to such areas and populations.

2. To determine whether the operation of the proposed station would involve objectionable interference with Stations KWCR, Cedar Rapids, Iowa; WCVS, Springfield, Illinois; WHFC, Cicero, Illinois; WMBD, Peoria, Illinois or with any other existing broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

3. To determine whether the operation of the proposed station would involve objectionable interference with the services proposed in any other pending applications for broadcast facilities, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

4. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and standards of Good Engineering Practice Concerning Standard Broadcast Stations.

It is further ordered, That Cedar Rapids Broadcasting Corporation; WCBS, Incorporated; WHFC, Incorporated; and Peoria Broadcasting Company, licensees of Stations KWCR, Cedar Rapids, Iowa; WCVS, Springfield, Illinois; WHFC, Cicero, Illinois; and WMBD, Peoria, Illinois, respectively, are made parties to the proceeding.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12502; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket No. 9860]

ROYAL BROADCASTING CO.

ORDER DESIGNATING APPLICATION FOR HEARING OF STATED ISSUES

In re application of Arthur Wilson Davis tr/as Royal Broadcasting Company, Lancaster, South Carolina, for construction permit; Docket No. 9860, File No. BP-7547.

At a session of the Federal Communications Commission held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration the above-entitled application for a new standard broadcast station to be operated on the frequency 1220 kilocycles with a power of 1 kilowatt, daytime only at Lancaster, South Carolina;

It appearing, that the applicant is legally, technically, financially and otherwise qualified to operate the proposed station but that the application may involve interference with one or more existing stations and otherwise not comply with the Standards of Good Engineering Practice;

It is ordered, That pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application is designated for hearing commencing at 10:00 a. m. on February 2, 1951, at Washington, D. C., upon the following issues:

1. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed station, and the character of other broadcast service available to such areas and populations.

2. To determine whether the operation of the proposed station would involve objectionable interference with Station WADE, Wadesboro, North Carolina, or with any other existing broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

3. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and standards of Good Engineering Practice Concerning Standard Broadcast Stations.

It is further ordered, That Robert Phillip Lyon and Risden A. Lyon, d/b as R. P. Lyon and Son, licensee of Station WADE, Wadesboro, North Carolina is made a party to this proceeding.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12503; Filed, Dec. 29, 1950; 8:50-a. m.]

[Docket No. 9861]

SUNBURY BROADCASTING CORP. (WKOK)

ORDER DESIGNATING APPLICATION FOR HEARING ON STATED ISSUES

In re application of Sunbury Broadcasting Corporation (WKOK), Sunbury, Pennsylvania, for construction permit; Docket No. 9861, File No. BP-7685.

At a session of the Federal Communications Commission held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration the above-entitled application of Sunbury Broadcasting Corporation requesting a construction permit to change type transmitter and make changes in the antenna system of Station WKOK, Sunbury, Pennsylvania, presently operating on the frequency 1240 kilocycles, with 250 watts power, unlimited time;

It appearing, that the applicant is legally, technically, financially and otherwise qualified to operate Station WKOK as proposed, but that the application may involve interference with one or more existing stations and otherwise not comply with the Standards of Good Engineering Practice;

It is ordered, That, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application is designated for hearing commencing at 10:00 a. m. on February 5, 1951, at Washington, D. C., upon the following issues:

1. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed station, and the character of other broadcast service available to such areas and populations.

2. To determine whether the operation of Station WKOK, as proposed, would involve objectionable interference with Stations WBAX, Wilkes-Barre, Pennsylvania, and WHUM, Reading, Pennsylvania, or any other existing broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

3. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and standards of Good Engineering Practice Concerning Standard Broadcast Stations.

It is further ordered, That John H. Stenger, Jr., licensee of Station WBAX Wilkes-Barre, Pennsylvania, and Eastern Radio Corp., licensee of Station WHUM, Reading, Pennsylvania, are made parties to this proceeding.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12504; Filed, Dec. 29, 1950; 8:50 a. m.]

[Docket No. 9637]

RADIO ATHENS, INC. (WRFC)

ORDER DESIGNATING APPLICATION FOR HEARING ON STATED ISSUES

In re application of Radio Athens, Inc. (WRFC), Athens, Georgia, for construction permit; Docket No. 9637, File No. BP-7415.

At a session of the Federal Communications Commission held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration the above-entitled application requesting a construction permit to change the facilities of Station WRFC at Athens, Georgia, from 960 kilocycles, with 1 kilowatt power, daytime only to 960 kilocycles, 500 watts power night and 1 kilowatt day (LS), unlimited time utilizing a directional antenna for night use only;

It appearing, that the applicant is legally, technically, financially and otherwise qualified to operate Station WRFC, as proposed, that no interference would be caused to any existing or proposed station but that the application may otherwise not comply with the Standards of Good Engineering Practice; particularly with reference to coverage of the city of Athens, Georgia, the areas and populations which may be expected to receive satisfactory nighttime service, the assignment of stations where ob-

jectionable interference would be received to a field intensity contour greater than that specified for a station of its class and the percentage of the population of the city of Athens residing within the 250 mv/m contour;

It is ordered, That pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application is designated for hearing commencing at 10:00 a. m. on February 5, 1951, at Washington, D. C., upon the following issues:

1. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed stations, and the character of other broadcast service available to such areas and populations.

2. To determine whether the installation and operation of the proposed stations would be in compliance with the Commission's rules and standards of Good Engineering Practice Concerning Standard Broadcast Stations with particular reference to coverage of the city of Athens, Georgia, the areas and populations which may be expected to receive satisfactory nighttime service, the assignment of stations where objectionable interference would be received to a field intensity contour greater than that specified for a station of its class and the percentage of the population of the city of Athens residing within the 250 mv/m contour.

FEDERAL COMMUNICATIONS COMMISSION
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12505; Filed, Dec. 29, 1950; 8:51 a. m.]

[Docket Nos. 9487, 9862, 9863]

CENTRAL OHIO BROADCASTING CO. ET AL.

ORDER DESIGNATING APPLICATIONS FOR CONSOLIDATED HEARING ON STATED ISSUES

In re applications of Homer Akers, Charles V. Lundstedt and Emmitt Akers, d/b as Central Ohio Broadcasting Company, Galion, Ohio, Docket No. 9487, File No. BP-7031; Frederick Eckardt, Beatrice B. Eckardt and Woodrow C. Eckardt d/b as Fayette Broadcasting Company, Washington Court House, Ohio, Docket No. 9862, File No. BP-7860; The Court House Broadcasting Company, Washington Court House, Ohio, Docket No. 9863, File No. BP-7881; for construction permits.

At a session of the Federal Communications Commission held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration the above-entitled applications of Central Ohio Broadcasting Company requesting a permit to construct a new standard broadcast station to operate on frequency 1250 kilocycles, with 1 kilowatt (DA-2) power, unlimited time; of Fayette Broadcasting Company requesting a permit to construct a new standard broadcast station to operate on frequency 1250 kilocycles, with 500 watts power, daytime only; and of The Court House Broadcasting Company requesting a permit to construct a new standard broadcast station to operate on frequency 1250 kilocycles, with 250 watts power, daytime only; at the places specified above;

It is ordered, That, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said applications are designated for hearing in a consolidated proceeding commencing at 10:00 a. m. on February 7, 1951, at Washington, D. C., upon the following issues:

1. To determine the legal, technical, financial and other qualifications of the applicant partnerships and the partners and of the applicant corporation, its officers, directors and stockholders to construct and operate the proposed stations.

2. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed stations, and the character of other broadcast service available to such areas and populations.

3. To determine the type and character of program service proposed to be rendered and whether it would meet the requirements of the populations and areas proposed to be served.

4. To determine whether the operation of the proposed stations would involve objectionable interference with stations WDOK, Cleveland, Ohio; WGL, Fort Wayne, Indiana, or with any other existing broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

5. To determine whether the operation of the proposed stations would involve objectionable interference, each with the other, or with the services proposed in any other pending applications for broadcast facilities, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

6. To determine whether the installation and operation of the proposed stations would be in compliance with the Commission's rules and standards of Good Engineering Practice Concerning Standard Broadcast stations with particular reference to whether the operation proposed in the application of The Court House Broadcasting Company would be in compliance with those provisions pertaining to the assignment of Class IV stations to regional channels.

7. To determine the overlap, if any, that will exist between the service areas of the station proposed in the application of Fayette Broadcasting Company and the station proposed in the application of Skywave Broadcasting Corporation (File Number BP-7655, Docket number 9742), the nature and extent thereof, and whether such overlap, if any, is in contravention of § 3.35 of the Commission's rules.

8. To determine on a comparative basis which, if any, of the applications in this consolidated proceeding should be granted.

It is further ordered, That The Civic Broadcasters, Incorporated and News Sentinel Broadcasting Company, Incorporated, licensees of stations WDOK, Cleveland, Ohio and WGL, Fort Wayne, Indiana respectively, are made parties to the proceeding.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12506; Filed, Dec. 29, 1950; 8:51 a. m.]

[Docket No. 9864]

WILLIAMSBURG RADIO CO., INC.

ORDER DESIGNATING APPLICATION FOR HEARING ON STATED ISSUES

In re application of Williamsburg Radio Company, Inc., Williamsburg, Virginia, for construction permit; Docket No. 9864, File No. BP-7729.

At a session of the Federal Communications Commission held at its offices in Washington, D. C., on the 13th day of December 1950;

The Commission having under consideration the above-entitled application requesting a permit to construct a new standard broadcast station to operate on frequency 740 kilocycles, with 1 kilowatt power, daytime only, at Williamsburg, Virginia;

It appearing, that the applicant is legally, technically, financially and otherwise qualified to operate the proposed station, except as to matter covered by Issue 6, below, but that the application may involve interference with one or more existing stations and otherwise not comply with the Standards of Good Engineering Practice;

It is ordered, That, pursuant to section 309 (a) of the Communications Act of 1934, as amended, the said application is designated for hearing at 10:00 a. m. on February 7, 1951, at Washington, D. C., upon the following issues:

1. To determine the areas and populations which may be expected to gain or lose primary service from the operation of the proposed station, and the character of other broadcast service available to such areas and populations.

2. To determine whether the operation of the proposed station would involve objectionable interference with Stations WCVH, Chester, Pennsylvania; WMBL, Morehead City, North Carolina, or with any other existing broadcast stations, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

3. To determine whether the operation of the proposed station would involve objectionable interference with the services proposed in any other pending applications for broadcast facilities, and, if so, the nature and extent thereof, the areas and populations affected thereby, and the availability of other broadcast service to such areas and populations.

4. To determine whether the operation of the proposed station would involve second harmonic interference with Stations WBBL, Richmond, Virginia, and WLEE, Richmond, Virginia, and, if so, the nature and extent thereof, the areas and populations affected thereby, and

the availability of other broadcast service to such areas and populations.

5. To determine whether the installation and operation of the proposed station would be in compliance with the Commission's rules and standards of Good Engineering Practice Concerning Standard Broadcast Stations.

6. To determine the overlap, if any, that will exist between the service areas of the proposed station and of Station WXGI, Richmond, Virginia, the nature and extent thereof, and whether such overlap, if any, is in contravention of § 3.35 of the Commission's rules.

It is further ordered, That James M. Tisdale; Carteret Broadcasting Company; Grace Covenant Presbyterian Church; and Lee Broadcasting Corporation, licensees of Stations WVCH, Chester, Pennsylvania; WMBL, Morehead City, North Carolina; WBBL, Richmond, Virginia; and WLEE, Richmond, Virginia, respectively, are made parties to the proceeding.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50–12507; Filed, Dec. 29, 1950; 8:51 a. m.]

RADIOCOMMUNICATION BETWEEN AMATEUR STATIONS OF DIFFERENT COUNTRIES

DECEMBER 21, 1950.

Communications between amateur radio stations licensed by the Federal Communications Commission and foreign amateur stations are permissible subject to the limitations of section 1 of Article 42 of the Radio Regulations Annexed to the International Telecommunications Convention (Atlantic City, 1947). Section 1 of this article provides as follows:

Radiocommunications between amateur stations of different countries shall be forbidden if the administration of one of the countries concerned has notified that it objects to such radiocommunications.

According to information obtained by the Commission from the Department of State, to and including October 13, 1950, certain foreign countries object to the exchange, internationally, of amateur radio communications and others impose specific limitations upon such communications. The names of the countries forbidding exchange, internationally, of amateur communications and countries imposing restrictions on such exchange, together with the terms of the restrictions, are hereinafter set forth.

ADMINISTRATIONS WHICH FORBID RADIO COMMUNICATIONS BETWEEN THEIR AMATEUR STATIONS AND AMATEUR STATIONS IN OTHER COUNTRIES

Indonesia, Japan (excluding amateur stations of Allied Occupation Forces as authorized by the Supreme Commander, Allied Powers).

ADMINISTRATIONS WHICH FORBID ALL AMATEUR RADIO OPERATION

Indo-China, Iran, Lebanon, Netherlands Antilles, Thailand.

THE FOLLOWING ADMINISTRATIONS HAVE PLACED THE SPECIAL RESTRICTIONS NOTED ON AMATEUR RADIOCOMMUNICATIONS

Australia (Commonwealth of): Amateur stations in Australia are authorized to conduct radiocommunications for purely experimental purposes with amateur stations in other countries and the administrations of which permit such radiocommunications.

Austria: The reception of foreign amateur station transmissions is permitted, but transmissions by Austrian amateur stations are strictly forbidden by the Allied control authorities in Austria.

Accordingly, United States amateur licensees are warned that international communications are limited by treaty as indicated above. The foregoing does not in any way modify and should not be confused with the provisions of section 2 of Article 42 of the International Radio Regulations (Atlantic City, 1947) which prohibits the use of amateur stations for transmitting international communications on behalf of third parties except when permitted by special arrangements between the countries concerned.

This notice supersedes and cancels public notices of October 12, 1949 (Mimeo. No. 41636) and November 4, 1949 (Mimeo. No. 42642).

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50–12508; Filed, Dec. 29, 1950; 8:51 a. m.]

[Docket No. 9834]

GREAT NORTHERN RADIO, INC. (WWSC)

ORDER CONTINUING HEARING

In the matter of Great Northern Radio, Inc. (WWSC), Glens Falls, New York, applicant for modification of construction permit; Docket No. 9834, File No. BMP–5335.

The Commission having under consideration a motion filed December 5, 1950, by Great Northern Radio, Inc. (WWSC), Glens Falls, New York, for a 60-day continuance of the hearing on its above-entitled application, now scheduled for 10:00 o'clock a. m. Friday, December 15, 1950, in Washington, D. C.; and

It appearing, that on November 24, 1950, the applicant filed with the Commission a petition seeking reconsideration of the action of the Commission designating said application for hearing and for a grant without hearing; that said petition has not yet received Commission consideration; that if said petition for reconsideration be granted a hearing will be obviated; that a grant of said petition would serve the public interest and would conduce to the dispatch of the Commission's business; and

It further appearing, that there are no other parties to this proceeding and that Commission Counsel has consented to a waiver of § 1.745 so as to permit early consideration of this petition;

It is ordered, This 8th day of December 1950, that the petition for continuance is granted; and the hearing on the above-entitled application is hereby continued to 10:00 o'clock a. m. Monday, February 12, 1951.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50–12509; Filed, Dec. 29, 1950; 8:51 a. m.]

[Docket No. 9641, 9809, 9810]

DAVID M. BALTIMORE ET AL.

ORDER CONTINUING HEARING

In re applications of David M. Baltimore, Scranton, Pennsylvania, Docket No. 9641, File No. BP–7541; The Scranton Times (co-partnership), Elizabeth R. Lynett and Edward J. Lynett, Jr. (WQAN), Scranton, Pennsylvania, Docket No. 9809, File No. BP–7791; Richard G. Evans tr/as Radio Pittston FM and Television Company, Pittston, Pennsylvania, Docket No. 9810, File No. BP–7815; for construction permits.

The Commission having under consideration a petition filed December 5, 1950, by The Scranton Times (WQAN), Scranton, Pennsylvania, requesting a continuance of the hearing presently scheduled for January 2, 1951, at Washington, D. C., in the proceeding upon the above-entitled applications for construction permits; and

It appearing, That no opposition to the granting of the instant petition has been filed with the Commission;

It is ordered, This 15th day of December 1950, that the petition is granted; and that the hearing in the proceeding upon the above-entitled applications is continued to 10:00 a. m., Monday, January 22, 1951, at Washington, D. C.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50–12510; Filed, Dec. 29, 1950; 8:51 a. m.]

[Docket No. 9758]

COASTWISE LINE; SS WILLIAM BLACK YATES

ORDER CONTINUING HEARING

In the matter of petition of the Coastwise Line requesting reconsideration by the Commission of its denial of the application of Coastwise Line for relief from forfeitures imposed in connection with the sailing of the SS "William Black Yates" in violation of sections 351 and 353 of the Communications Act of 1934, as amended; Docket No. 9758.

The Commission having under consideration a petition filed December 14, 1950, by the Coastwise Line, requesting continuance until a date not earlier than February 19, 1951, of the hearing on the above-entitled proceeding presently scheduled for January 4, 1951, at Washington, D. C.; and

It appearing, that because persons having knowledge of the facts are found or reside at great distances from the

place of hearing, counsel for the petitioner and counsel for the Commission have agreed to stipulate the facts material to the case on which there is no disagreement; and

It further appearing, that, in order to arrive at such stipulation, it is necessary to study the deposition of Olaf K. Clausen, Master of the SS "William Black Yates" during the period of the above-mentioned violation taken in Los Angeles, California; and that such deposition will not be received at the Commission's offices in Washington, D. C., before the week of December 18, 1950; and

It further appearing, that good and sufficient cause has been shown for the granting of such petition and no opposition to the grant thereof has been filed;

It is ordered, This 19th day of December 1950, that the hearing in the above-entitled proceeding, now scheduled for January 4, 1951, be, and it is hereby, continued until March 2, 1951.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] T. J. SLOWIE,
Secretary.

[F. R. Doc. 50-12511; Filed, Dec. 29, 1950; 8:51 a. m.]

FEDERAL POWER COMMISSION

[Docket No. G-1172]

INDEPENDENT NATURAL GAS CO.

ORDER FIXING DATE OF HEARING

DECEMBER 21, 1950.

On March 29, 1950, when this matter was called for hearing as provided by order of March 13, 1950, counsel for Independent Natural Gas Company requested a continuance, and the hearing was recessed to a date to be fixed by the Commission.

The Commission orders: Hearing in this matter be held commencing on January 17, 1951, at 10:00 a. m., e. s. t., in the Hearing Room of the Federal Power Commission, 1800 Pennsylvania Avenue NW., Washington, D. C.

Date of issuance: December 26, 1950.

By the Commission.

[SEAL] J. H. GUTRIDE,
Acting Secretary.

[F. R. Doc. 50-12479; Filed, Dec. 29, 1950; 8:47 a. m.]

[Docket No. G-1471]

TEXAS GAS TRANSMISSION CORP.

ORDER FIXING DATE OF HEARING

DECEMBER 22, 1950.

On August 28, 1950, Texas Gas Transmission Corporation (Applicant), a Delaware Corporation with its principal place of business at Owensboro, Kentucky, filed an application for a certificate of public convenience and necessity pursuant to section 7 of the Natural Gas Act, as amended, to construct and operate certain facilities, subject to the jurisdiction of the Commission, as are fully described in such application on file with the Commission and open to public inspection.

Applicant has requested that this application be heard under the shortened procedure provided for by § 1.32 (b) of the Commission's rules of practice and procedure; no request to be heard or protest has been filed subsequent to giving of due notice of the filing of the application, including publication in the FEDERAL REGISTER on September 19, 1950 (15 F. R. 6275).

The Commission finds:

This proceeding is a proper one for disposition under the provisions of § 1.32 (b) (18 CFR 1.32) of the Commission's rules of practice and procedure.

The Commission orders:

(A) Pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act, as amended, and the Commission's rules of practice and procedure, a hearing be held on January 16, 1951, at 9:30 o'clock a. m., e. s. t., in the Hearing Room of the Federal Power Commission, 1800 Pennsylvania Avenue NW., Washington, D. C., concerning the matters involved and the issues presented by such application: *Provided, however*, That the Commission may, after a non-contested hearing, forthwith dispose of the proceeding pursuant to the provisions of § 1.32 (b) of the Commission's rules of practice and procedure.

(B) Interested State commissions may participate as provided by §§ 1.8 and 1.37 (f) (18 CFR 1.8 and 1.37 (f)) of the said rules of practice and procedure.

Date of issuance: December 26, 1950.

By the Commission.

[SEAL] J. H. GUTRIDE,
Acting Secretary.

[F. R. Doc. 50-12480; Filed, Dec. 29, 1950; 8:47 a. m.]

[Docket No. G-1553]

CANADIAN RIVER GAS CO.

NOTICE OF APPLICATION

DECEMBER 26, 1950.

Take notice that Canadian River Gas Company (Applicant), a Delaware corporation of Amarillo, Texas, filed on December 11, 1950, an application for a certificate of public convenience and necessity pursuant to section 7 of the Natural Gas Act authorizing the use and operation of 15,279 feet of 4½-inch O. D. natural gas pipeline, 12,872 feet of 6⅝-inch O. D. natural gas pipeline, a 6-inch meter run and a 3-inch regulator, which facilities were installed at or near Clayton, New Mexico, and replaced 28,151 feet of 3½-inch O. D. pipeline, a 4-inch meter run and a 2-inch regulator.

The application states that the service being rendered by the new facilities is that of meeting increased maximum hourly demands of its resale customer, Clayton Gas Company, at Clayton, New Mexico. It is also stated that removal of the old facilities was completed on October 1, 1950, and that the new facilities were placed in operation on September 28, 1950.

The total over-all cost of the facilities was $44,530, which was financed by Applicant under the terms of its agreement with Colorado Interstate Gas Company, dated January 3, 1928.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington 25, D. C., in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before the 15th day of January 1951. The application is on file with the Commission for public inspection.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 50-12519; Filed, Dec. 29, 1950; 8:53 a. m.]

GENERAL SERVICES ADMINISTRATION

SECRETARY OF DEFENSE

DELEGATION OF AUTHORITY WITH RESPECT TO PROPOSED RELEASED VALUATION RATINGS BY RAIL CARRIERS

Protest before Joint Official, Southern and Western Classification Committees of rail carriers proposed released valuation ratings and publication of new item ratings on engines, steam or internal combustion, noibn, etc., carried under subject No. 66, Joint Docket No. 141.

1. Pursuant to the provisions of sections 201 (a) (4) and 205 (d) and (e) of the Federal Property and Administrative Services Act of 1949, Public Law 152, 81st Congress, authority to represent the interests of the executive agencies of the Federal Government and to appear as witnesses for the executive agencies of the Federal Government in the matter of proposed released valuation ratings by the rail carriers on engines, steam or internal combustion, noibn, and the publication of new items providing ratings on engines, steam or internal combustion, jet propulsion type, and engines, steam or internal combustion, radial cylinder type, covered by Subject No. 66, Joint Docket No. 141, of the Official, Southern, and Western Classification, before the Joint Official, Southern and Western Classification Committee, set for hearing on November 28, 1950, is hereby delegated to the Secretary of Defense.

2. The Secretary of Defense is hereby authorized to redelegate any of the authority contained herein to any officer, official or employee of the Department of Defense.

3. The authority conferred herein shall be exercised in accordance with the policies, procedures and controls prescribed by the General Services Administration and shall further be exercised in co-operation with the responsible officers, officials and employees of such administration.

4. This delegation of authority shall be effective as of November 28, 1950.

Dated: December 22, 1950.

JESS LARSON,
Administrator.

[F. R. Doc. 50-12521; Filed, Dec. 29, 1950; 8:53 a. m.]

INTERSTATE COMMERCE COMMISSION

[4th Sec. Application 25694]

LATEX FROM AKRON, OHIO, TO AUSTELL, GA.

APPLICATION FOR RELIEF

DECEMBER 27, 1950.

The Commission is in receipt of the above-entitled and numbered application for relief from the long-and-short-haul provision of section 4 (1) of the Interstate Commerce Act.

Filed by: L. C. Schuldt, Agent, for carriers parties to his staff I. C. C. No. 4300, pursuant to fourth-section order No. 9800.

Commodities involved: Latex (liquid crude rubber), carloads.

From: Akron, Ohio.

To: Austell, Ga.

Grounds for relief: Circuitous routes.

Any interested person desiring the Commission to hold a hearing upon such application shall request the Commission in writing so to do within 15 days from the date of this notice. As provided by the general rules of practice of the Commission, Rule 73, persons other than applicants should fairly disclose their interest, and the position they intend to take at the hearing with respect to the application. Otherwise the Commission, in its discretion, may proceed to investigate and determine the matters involved in such application without further or formal hearing. If because of an emergency a grant of temporary relief is found to be necessary before the expiration of the 15-day period, a hearing, upon a request filed within that period, may be held subsequently.

By the Commission, Division 2.

[SEAL] W. P. BARTEL, *Secretary.*

[F. R. Doc. 50-12512; Filed, Dec. 29, 1950; 8:52 a. m.]

[4th Sec. Application 25695]

CITRUS FRUIT FROM FLORIDA TO ILLINOIS AND OFFICIAL TERRITORIES

APPLICATION FOR RELIEF

DECEMBER 27, 1950.

The Commission is in receipt of the above-entitled and numbered application for relief from the long-and-short-haul provision of section 4 (1) of the Interstate Commerce Act.

Filed by: D. Q. Marsh, Agent, for carriers parties to Agent C. A. Spaninger's tariff I. C. C. No. 642, pursuant to fourth-section order No. 16101.

Commodities involved: Citrus fruit, carloads.

From: Florida.

To: Illinois and official territories.

Grounds for relief: Competition with rail carriers.

Any interested person desiring the Commission to hold a hearing upon such application shall request the Commission in writing so to do within 15 days from the date of this notice. As provided by the general rules of practice of the Commission, Rule 73, persons other than applicants should fairly disclose their interest, and the position they intend to take at the hearing with respect to the application. Otherwise the Commission, in its discretion, may proceed to investigate and determine the matters involved in such application without further or formal hearing. If because of an emergency a grant of temporary relief is found to be necessary before the expiration of the 15-day period, a hearing, upon a request filed within that period, may be held subsequently.

By the Commission, Division 2.

[SEAL] W. P. BARTEL, *Secretary.*

[F. R. Doc. 50-12513; Filed, Dec. 29, 1950; 8:52 a. m.]

[4th Sec. Application 25696]

PAPER BOXES FROM BOGALUSA, LA., TO ST. LOUIS, MO., AND EAST ST. LOUIS, ILL.

APPLICATION FOR RELIEF

DECEMBER 27, 1950.

The Commission is in receipt of the above-entitled and numbered application for relief from the long-and-short-haul provision of section 4 (1) of the Interstate Commerce Act.

Filed by: D. Q. Marsh, Agent, for Gulf, Mobile and Ohio Railroad Company and St. Louis-San Francisco Railway Company, pursuant to fourth-section order No. 16101.

Commodities involved: Boxes, fibreboard, pulpboard or strawboard, carloads.

From: Bogalusa, La.

To: St. Louis, Mo., and East St. Louis, Ill.

Grounds for relief: Competition with rail carriers.

Any interested person desiring the Commission to hold a hearing upon such application shall request the Commission in writing so to do within 15 days from the date of this notice. As provided by the general rules of practice of the Commission, Rule 73, persons other than applicants should fairly disclose their interest, and the position they intend to take at the hearing with respect to the application. Otherwise the Commission, in its discretion, may proceed to investigate and determine the matters involved in such application without further or formal hearing. If because of an emergency a grant of temporary relief is found to be necessary before the expiration of the 15-day period, a hearing, upon a request filed within that period, may be held subsequently.

By the Commission, Division 2.

[SEAL] W. P. BARTEL, *Secretary.*

[F. R. Doc. 50-12514; Filed, Dec. 29, 1950; 8:52 a. m.]

[4th Sec. Application 25697]

PETROLEUM PRODUCTS FROM MOBILE, ALA., TO POINTS IN ALABAMA

APPLICATION FOR RELIEF

DECEMBER 27, 1950.

The Commission is in receipt of the above-entitled and numbered application for relief from the long-and-short-haul provision of section 4 (1) of the Interstate Commerce Act.

Filed by: R. E. Boyle, Jr., Agent, for The Alabama Great Southern Railroad Company and other carriers named in the application.

Commodities involved: Petroleum products, in tank-car loads.

From: Mobile, Ala.

To: Points in Alabama.

Grounds for relief: Competition with rail carriers. To meet intrastate rates.

Schedules filed containing proposed rates: C. A. Spaninger's tariff I. C. C. No. 1065, Supp. 192.

Any interested person desiring the Commission to hold a hearing upon such application shall request the Commission in writing so to do within 15 days from the date of this notice. As provided by the general rules of practice of the Commission, Rule 73, persons other than applicants should fairly disclose their interest, and the position they intend to take at the hearing with respect to the application. Otherwise the Commission, in its discretion, may proceed to investigate and determine the matters involved in such application without further or formal hearing. If because of an emergency a grant of temporary relief is found to be necessary before the expiration of the 15-day period, a hearing, upon a request filed within that period, may be held subsequently.

By the Commission, Division 2.

[SEAL] W. P. BARTEL, *Secretary.*

[F. R. Doc. 50-12515; Filed, Dec. 29, 1950; 8:52 a. m.]

[4th Sec. Application 25698]

IRON AND STEEL ARTICLES FROM GENEVA, UTAH, TO W. T. L. TERRITORY

APPLICATION FOR RELIEF

DECEMBER 27, 1950.

The Commission is in receipt of the above-entitled and numbered application for relief from the long-and-short-haul provision of section 4 (1) of the Interstate Commerce Act.

Filed by: L. E. Kipp, Agent, for carriers parties to his tariff I. C. C. No. A-3560.

Commodities involved: Iron and steel pipe or tubing, tanks and cylinders, etc., carloads.

From: Geneva, Utah.

To: Points in Colorado, Kansas, Missouri, Nebraska, and Wyoming.

Grounds for relief: Circuitous routes, to maintain grouping, and to apply over short tariff routes rates constructed on

the basis of the short line distance formula.

Schedules filed containing proposed rates: L. E. Kipp's tariff I. C. C. No. A-3560, Supp. 156.

Any interested person desiring the Commission to hold a hearing upon such application shall request the Commission in writing so to do within 15 days from the date of this notice. As provided by the general rules of practice of the Commission, Rule 73, persons other than applicants should fairly disclose their interest, and the position they intend to take at the hearing with respect to the application. Otherwise the Commission, in its discretion, may proceed to investigate and determine the matters involved in such application without further or formal hearing. If because of an emergency a grant of temporary relief is found to be necessary before the expiration of the 15-day period, a hearing, upon a request filed within that period, may be held subsequently.

By the Commission, Division 2.

[SEAL] W. P. BARTEL, *Secretary.*

[F. R. Doc. 50-12516; Filed, Dec. 29, 1950; 8:52 a. m.]

[4th Sec. Application 25699]

IMPORT FERTILIZER MATERIALS FROM BRAITHWAITE, LA., TO SOUTH

APPLICATION FOR RELIEF

DECEMBER 27, 1950.

The Commission is in receipt of the above-entitled and numbered application for relief from the long-and-short-haul provision of section 4 (1) of the Interstate Commerce Act.

Filed by: R. E. Boyle, Jr., Agent, for carriers parties to Agent C. A. Spaninger's tariff I. C. C. No. 962.

Commodities involved: Import fertilizer materials, carloads.

From: Braithwaite, La.

To: Southern territory.

Grounds for relief: Competition with rail carriers. Circuitous routes.

Schedules filed containing proposed rates: C. A. Spaninger's tariff I. C. C. No. 962, Supp. 43.

Any interested person desiring the Commission to hold a hearing upon such application shall request the Commission in writing so to do within 15 days from the date of this notice. As provided by the general rules of practice of the Commission, Rule 73, persons other than applicants should fairly disclose their interest, and the position they intend to take at the hearing with respect to the application. Otherwise the Commission, in its discretion, may proceed to investigate and determine the matters involved in such application without further or formal hearing. If because of an emergency a grant of temporary relief is found to be necessary before the expiration of the 15-day period, a hearing, upon a request filed within that period, may be held subsequently.

By the Commission, Division 2.

[SEAL] W. P. BARTEL, *Secretary.*

[F. R. Doc. 50-12517; Filed, Dec. 29, 1950; 8:52 a. m.]

SECURITIES AND EXCHANGE COMMISSION

[File No. 1-321]

HALE BROS. STORES, INC.

NOTICE OF APPLICATION TO WITHDRAW FROM LISTING AND REGISTRATION, AND OF OPPORTUNITY FOR HEARING

At a regular session of the Securities and Exchange Commission, held at its office in the city of Washington, D. C., on the 26th day of December A. D. 1950.

Hale Bros. Stores, Inc., a Delaware corporation, pursuant to section 12 (d) of the Securities Exchange Act of 1934 and Rule X-12D2-1 (b) promulgated thereunder, has made application to withdraw from registration and listing on the San Francisco Stock Exchange its No Par Value Common Stock.

The application for withdrawal alleges the following:

(1) 291,300 shares of No Par Value Common Stock of the applicant were issued and outstanding in the hands of the public prior to March 17, 1950.

(2) The applicant entered into an agreement dated March 17, 1950, with Broadway Department Store, Inc., a Delaware corporation, providing for a plan of reorganization.

(3) Pursuant to the provisions of this plan of reorganization, holders of 289,070 shares of Common Stock of the applicant had exchanged such shares for Common Stock of Broadway Department Store, Inc., as of November 16, 1950.

(4) As a result of the above described exchange of shares pursuant to this plan of reorganization on November 16, 1950, 2,230 shares of applicant's No Par Value Common Stock remained outstanding in the hands of 36 shareholders.

(5) The San Francisco Stock Exchange suspended the No Par Value Common Stock of applicant from trading on that exchange on August 31, 1950 by reason of the small number of shares of stock outstanding in the hands of the public and by reason of the small number of shareholders.

(6) An auction market for the No Par Value Common Stock of applicant is no longer feasible by reason of the small number of shares outstanding in the hands of the public and the small number of shareholders.

(7) The applicant has complied with the rules of the San Francisco Stock Exchange with respect to withdrawing the security from registration and listing on that exchange.

Upon receipt of a request prior to January 31, 1951, from any interested person for a hearing in regard to terms to be imposed upon the delisting of this security, the Commission will determine whether to set the matter down for hearing. Such request should state briefly the nature of the interest of the person requesting the hearing and the position he proposes to take at the hearing with respect to imposition of terms or conditions. In addition, any interested person may submit his views or any additional facts bearing on this application by means of a letter addressed to the Secretary of the Securities and Exchange Commission, Washington, D. C. If no one requests a hearing on this matter, this application will be determined by order of the Commission on the basis of the facts stated in the application, and other information contained in the official file of the Commission pertaining to the matter.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12495; Filed, Dec. 29, 1950; 8:49 a. m.]

[File Nos. 59-10, 54-82, 59-39, 54-50, 54-147, 37-55]

NORTH AMERICAN CO. ET AL.

ORDER RELEASING JURISDICTION OVER FEES AND EXPENSES

At a regular session of the Securities and Exchange Commission, held at its office in the city of Washington, D. C., on the 21st day of December 1950.

In the matter of The North American Company and its subsidiary companies, File No. 59-10; The North American Company, File No. 54-82; North American Light & Power Company holding company system and The North American Company, File No. 59-39; North American Light & Power Company, File No. 54-50; Illinois Power Company, File No. 54-147.

In the matter of D. E. Ackers, North American Light & Power Company and The Kansas Power and Light Company, File No. 37-55.

The Commission by orders dated February 28, 1947, and June 25, 1947, having approved a plan filed under section 11 (e) of the Public Utility Holding Company Act of 1935 by The North American Company, a registered holding company, for the liquidation and dissolution of its subsidiary, North American Light & Power Company, also a registered holding company; and

Said orders having reserved jurisdiction over the payment of all fees and expenses payable in connection with the plan; and applications for payment of fees and expenses, and for approval of payments previously made having been filed by certain of the participants in the proceedings relating to the plan; and

Public hearings having been held on said applications and with respect to certain fees and expenses as to which no applications have been filed, the staff of the Division of Public Utilities of the Commission having issued a recom-

mended findings and opinion thereon, and the Commission having considered the record in such proceedings, and having this date issued its memorandum opinion adopting said recommended findings and opinion as its findings and opinion, modified as set forth in said memorandum opinion, and having concluded that the fees and expenses requested or paid in the amounts hereinafter set forth are not unreasonable;

It is ordered, That the reservation of jurisdiction in this matter with respect to the following fees and expenses be, and the same hereby is, released, on condition that payment of such fees and expenses, not heretofore paid, be made by the respective companies prior to December 29, 1950, and, further, on condition that out of such payments, or otherwise, Lawrence R. Condon and Percival E. Jackson refund to their clients in these proceedings the sums of $129,343.55 and $10,500, respectively:

PAYABLE BY NORTH AMERICAN LIGHT & POWER CO.

Recipient or applicant	Requested or paid	
	Fees	Expenses
Lawrence R. Condon	$400,000.00	$26,466.44
Percival E. Jackson	100,000.00	2,034.21
Nutter, McClennen & Fish	7,500.00	337.05
Louis Braun	10,000.00	
Doran, Kline, Cosgrove, Jeffrey & Russell	220,000.00	24,513.10
James F. Masterson	21,575.00	615.47
Schenker & Schenker	18,500.00	1,020.38
John Jirgal	125,400.00	9,018.31
D. E. Ackers	140,000.00	
Bell, Boyd & Marshall	2,000.00	804.42
Black & Veatch	2,691.20	418.54
William M. Hammond	600.00	110.50
William D. Pence	500.00	89.42
Nicholson, Porter & List	400.00	136.16
Charles H. Stevens	1,000.00	114.97
James Walker	1,000.00	140.40
First Boston Corp	3,000.00	
Barnes & Hill	3,700.00	
Roy Wenzlick & Co	3,438.06	
Berlack & Irmels	2,900.00	75.23
Daily, Diner, White & Fiedler	2,750.00	80.45
Richards, Layton & Finger	3,000.00	15.34
McDermott, Will & Emery	1,400.00	
Javits & Javits	3,500.00	
Poppenhusen, Johnson, Thompson & Raymond	500.00	20.50
Alexander C. Dick	1,000.00	
Houltrie Hitt	250.00	
Henry A. Ley	900.00	63.79
Stone & Webster Engineering Corp	200.00	53.08
Irwin, Bushman & Buchanan	240.00	
Verrill, Dana, Walker, Philbrick & Whitehouse	102.00	

PAYABLE BY THE NORTH AMERICAN CO

George Roeler	$20,000.00	$715.24
Trustees of Central States Electric Corp		816.44
Blue Ridge Corp		682.09
American Cities Power & Light Corp		227.37
Sullivan & Cromwell	500,000.00	10,909.28
The J. G. White Engineering Corp	78,222.33	3,998.35
Price, Waterhouse & Co	7,500.00	
Roy Wenzlick & Co	500.00	23.25

PAYABLE BY ILLINOIS POWER CO.

Mayer, Meyer, Austrian & Platt	$370,000.00	$34,779.27
Pam, Hurd & Reichmann	87,500.00	19,476.90
Shaw-Rutan, Inc	14,692.50	1,807.85
Sargent & Lundy	5,961.54	1,214.27
Arthur Anderson & Co	13,560.00	442.66
Drexel & Co	5,000.00	
Price, Waterhouse & Co	19,002.65	(1)
Clarence Turley	7,265.00	231.19

[1] Including disbursements.

It is further ordered, That the reservation of jurisdiction over fees and expenses contained in our said orders of February 28, 1947, and June 25, 1947, hereby is expressly continued except insofar as specifically released herein.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12486; Filed, Dec. 29, 1950; 8:47 a. m.]

[File No. 70-2434]

PHILADELPHIA CO. AND DUQUESNE LIGHT CO.

ORDER RELEASING JURISDICTION OVER FEES AND EXPENSES

At a regular session of the Securities and Exchange Commission, held at its office in the city of Washington, D. C., on the 21st day of December 1950.

Philadelphia Company ("Philadelphia"), a registered holding company and a subsidiary of Standard Gas and Electric Company and Standard Power and Light Corporation, both registered holding companies, and Duquesne Light Company ("Duquesne"), a public utility subsidiary of Philadelphia, having filed a joint application-declaration, and amendments thereto, pursuant to sections 6, 7, 9, 10, 11 (b), 12 (c) and 12 (f) of the Public Utility Holding Company Act of 1935 ("act") and Rules U-42, U-43 and U-50, promulgated thereunder, regarding the amendment of the charter of Duquesne; the issuance of securities by Duquesne, including $12,000,000 principal amount of bonds, $7,500,000 par value of 3¾ percent preferred stock ("Public Series") and $27,500,000 par value of 4 percent preferred stock ("Philadelphia Series"); the issuance of securities by Philadelphia; the acquisition of securities by Philadelphia and Duquesne; the retirement of all its then outstanding preferred stock by Duquesne; and the sale by Philadelphia to Duquesne of all the capital stock of a non-utility subsidiary of Philadelphia (all as more fully described in Holding Company Act Release No. 10044), and the Commission by order dated August 21, 1950 having granted said application and permitted said declaration to become effective, and said order having reserved jurisdiction with respect to all fees and expenses, and the allocation thereof, to be paid in connection with such transactions;

Applicants-declarants having filed a further amendment with respect to the estimated fees and expenses proposed to be paid by Duquesne as listed below:

Description of expenses	Allocable to—			Total
	Bonds	Public series preferred stock	Philadelphia series preferred stock	
Registration fee	$1,242	$777		$2,019
Federal documentary tax stamps	13,200	8,250		21,450
Printing registration statement, bidding papers, trust indentures, etc	17,400	11,600		29,000
Printing temporary bonds and engraving definitive bonds	14,300			14,300
Authentication of bonds	5,100			5,100
Signature company for use of signing machine for signing temporary bonds and definitive bonds	2,400			2,400
Mortgage recording fees	150			150
Preparation of temporary and definitive stock certificates		3,175		3,175
Issuance and registration of stock certificates		2,300		2,300
State qualification fees and expenses	2,000	2,000		4,000
Accounting fees and expenses: Haskins & Sells	1,000	600	$1,200	2,800
Legal fees:				
Reed, Smith, Shaw & McClay	12,000	8,000	5,000	25,000
Mudge, Stern, Williams & Tucker	1,000	1,750	1,625	4,375
Legal expenses:				
Reed, Smith, Shaw & McClay	1,222	816	509	2,547
Mudge, Stern, Williams & Tucker	103	183	167	453
Redemption agent fee			1,250	1,250
Advertising and mailing costs	1,200	1,600	675	3,475
Estimated extra labor costs of company	1,000	1,000	500	2,500
Telephone and telegraph tolls, traveling expenses, miscellaneous and contingencies	3,208	2,792	750	6,750
Total	76,525	44,843	11,676	133,044

It appearing that Cahill, Gordon, Zachry & Reindel, counsel for the successful bidders whose fees are to be paid by the underwriters, have requested a fee of $8,000 and expenses of $592.52 for services rendered in connection with the sale of the bonds, and a fee of $6,000 and expenses of $550, in connection with the sale of the Public Series preferred stock; and it having been stated by the applicants-declarants that the amounts shown above as alocable to the Philadelphia Series preferred stock represent, in each instance, one-half of the total estimated expenses in connection with the Philadelphia Series preferred stock and that the other one-half of said estimated expenses, or an aggregate of $11,676, will be paid by Philadelphia, and that Philadelphia will incur other expenses estimated not to exceed $200, including transfer taxes of $40 on the transfer of the capital stock of Cheswick and Harmar Railroad Company; and it appearing that such proposed allocations result in total estimated fees and expenses of $133,044 to be paid by Duquesne, and $11,876 to be paid by Philadelphia; and

Statements having been filed in support of the fees and expenses requested for the legal and accounting services, and the Commission having considered such statements and the record, as further amended, and finding that all the fees and expenses proposed to be paid herein are not unreasonable and that the proposed allocation thereof is ap-

propriate, and deeming it appropriate that jurisdiction with respect thereto be released:

It is ordered, That the jurisdiction heretofore reserved over fees and expenses herein be, and hereby is, released.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12485; Filed, Dec. 29, 1950; 8:47 a. m.]

[File No. 70-2516]

LONG BEACH GAS CO., INC., AND LONG ISLAND LIGHTING CO.

ORDER APPROVING PLAN

At a regular session of the Securities and Exchange Commission, held at its office in the city of Washington, D. C., on the 26th day of December A. D. 1950.

Long Island Lighting Company ("Long Island"), a registered holding company, and its subsidiary, Long Beach Gas Company, Inc. ("Long Beach"), having jointly filed, pursuant to section 11 (e) of the Public Utility Holding Company Act of 1935 ("act"), a plan, as amended, for the merger, as of June 30, 1950, of Long Beach into Long Island in the following manner:

Long Beach had outstanding, on September 30, 1950, the following securities and open account payable:

First mortgage 5 percent bonds due 1956	$692,400
Open account payable	1,214,228
Preferred stock, 7 percent, 3,225 shares	322,500
Common stock, 1,000 shares	100,000

All the above, except the first mortgage bonds, are held by Long Island. Long Island will assume the first mortgage bonds. The open account, preferred stock, and common stock will be cancelled.

Such plan, as amended, having been duly filed, and notice of said filing having been duly given, and the Commission not having received a request for hearing with respect to said plan, as amended, within the period specified in said notice, or otherwise, and not having ordered a hearing thereon; and

The Commission finding that the plan, as amended, is necessary to effectuate the provisions of section 11 (b) of the act and is fair and equitable to the persons affected by it, and deeming it appropriate to grant a request of applicants that the plan may be consummated forthwith:

It is hereby ordered, Pursuant to section 11 (e) of the act, and subject to the terms and conditions prescribed in Rule U-24, that (1) the plan, as amended, be, and the same hereby is, approved, and (2) the plan, as amended, may be consummated forthwith.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12484; Filed, Dec. 29, 1950; 8:47 a. m.]

E. F. HICKEY

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22d day of December 1950.

In the matter of E. F. Hickey, % Young Men's Christian Association, Oklahoma City, Okla.

I. The Commission's public official files disclose that E. F. Hickey, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948, or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in paragraph II hereof tends, if true to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public interest and for the protection of investors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in paragraph IV hereof on the 29th day of January 1951, at the main office of the Securities and Exchange Commission, located at 425 Second Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22d, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the Rules of Practice unless such decision is waived.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29th, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12487; Filed, Dec. 29, 1950; 8:47 a. m.]

[1] Filed as part of the original document.

BOB HIGGINS

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22d day of December 1950.

In the matter of Bob Higgins, Box 11, Wellston, Oklahoma.

I. The Commission's public official files disclose that Bob Higgins, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948 or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in paragraph II hereof tends, if true, to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public

interest and for the protection of investors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in paragraph IV hereof on the 29th day of January 1951, at the main office of the Securities and Exchange Commission, located at 425 Second Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22d, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the rules of practice unless such decision is waived.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29th, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12488; Filed, Dec. 29, 1950; 8:47 a. m.]

FREDERICK H. SAVAGE

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22d day of December 1950.

In the matter of Frederick H. Savage, 730 Fifth Avenue, New York City.

I. The Commission's public official files disclose that Frederick H. Savage, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948, or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in paragraph II hereof tends, if true, to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public interest and for the protection of investors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in Paragraph IV hereof on the 29th day of January 1951 at the main office of the Securities and Exchange Commission, located at 425 Second Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22d, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the rules of practice unless such decision is waived.

[1] Filed as part of the original document.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29th, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12489; Filed, Dec. 29, 1950; 8:47 a. m.]

ORVILLE LYMON LIKENS

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22d day of December 1950.

In the matter of Orville Lymon Likens, 706 NW 29th Street, Oklahoma City, Oklahoma.

I. The Commission's public official files disclose that Orville Lymon Likens, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948 or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in Paragraph II hereof tends, if true, to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public interest and for the protection of inves-

tors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in paragraph IV hereof on the 29th day of January 1951 at the main office of the Securities and Exchange Commission, located at 425 Second Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the Rules of Practice unless such decision is waived.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29th, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12490; Filed, Dec. 29, 1950; 8:48 a. m.]

JOHN TALLTON WALKER

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22d day of December 1950.

In the matter of John Tallton Walker, Washington-Youree Hotel, Shreveport, Louisiana.

I. The Commission's public official files disclose that John Tallton Walker, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948 or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in paragraph II hereof tends, if true, to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public interest and for the protection of investors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in paragraph IV hereof on the 29th day of January 1951 at the main office of the Securities and Exchange Commission, located at 425 Second Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22d, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the rules of practice unless such decision is waived.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29th, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12491; Filed, Dec. 29, 1950; 8:48 a. m.]

[1] Filed as part of the original document.

LOUIS R. SORESI

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22nd day of December 1950.

In the matter of Louis R. Soresi, 308 West 48th Street, New York City.

I. The Commission's public official files disclose that Louis R. Soresi, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948 or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in paragraph II hereof tends, if true, to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public interest and for the protection of investors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in paragraph IV hereof on the 29th day of January 1951 at the main office of the Securities and Exchange Commission, located at 425 Second Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22d, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the Rules of Practice unless such decision is waived.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29th, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12492; Filed, Dec. 29, 1950; 8:48 a. m.]

GLEN B. YOUNG

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22d day of December 1950.

In the matter of Glen B. Young, Olpe, Kansas.

I. The Commission's public official files disclose that Glen B. Young, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948 or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in paragraph II hereof tends, if true, to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public interest and for the protection of investors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in paragraph IV hereof on the 29th day of January, 1951 at the main office of the Securities and Exchange Commission, located at 425 Second Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22d, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the rules of practice unless such decision is waived.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29th, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS, *Secretary.*

[F. R. Doc. 50-12493; Filed, Dec. 29, 1950; 8:48 a. m.]

[1] Filed as part of the original document.

WILLIAM HERBERT WEST

ORDER FOR PROCEEDINGS AND NOTICE OF HEARING

At a regular session of the Securities and Exchange Commission held at its office in the city of Washington, D. C., on the 22d day of December 1950.

In the matter of William Herbert West, Valley Falls, Kansas.

I. The Commission's public official files disclose that William Herbert West, hereinafter referred to as registrant, is registered as a broker-dealer pursuant to section 15 (b) of the Securities Exchange Act of 1934.

II. The Records Officer of the Commission has filed with the Commission a statement, a copy of which is attached hereto and made a part hereof,[1] stating that registrant did not file with the Commission reports of his financial condition during the calendar years 1943, 1944, 1945, 1946, 1947, 1948, or 1949 as required by section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted thereunder.

III. The information reported to the Commission by its Records Officer as set forth in paragraph II hereof tends, if true, to show that registrant violated section 17 (a) of the Securities Exchange Act of 1934 and Rule X-17A-5 adopted under said section.

IV. The Commission, having considered the aforesaid information, deems it necessary and appropriate in the public interest and for the protection of investors that proceedings be instituted to determine:

(a) Whether the statements set forth in paragraph II hereof are true;

(b) Whether registrant has wilfully violated section 17 (a) of the Securities

Exchange Act of 1934 and Rule X-17A-5 adopted under said section;

(c) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, it is in the public interest to revoke registration of registrant; and

(d) Whether, pursuant to section 15 (b) of the Securities Exchange Act of 1934, pending final determination, it is necessary or appropriate in the public interest or for the protection of investors to suspend the registration of registrant.

V. *It is ordered*, That registrant be given an opportunity for hearing as set forth in paragraph IV hereof on the 29th day of January 1951, at the main office of the Securities and Exchange Commission, located at 425 2d Street NW., Washington 25, D. C., before a Hearing Examiner to be designated by the Commission. On such date the Hearing Room Clerk in Room 101, North Building, will advise the parties and the Hearing Examiner as to the room in which such hearing will be held. The Commission will consider any motion with respect to a change of place of said hearing if said motion is filed with the Secretary of the Commission on or before January 22, 1951. Upon completion of any such hearing in this matter the Hearing Examiner shall prepare a recommended decision pursuant to Rule IX of the rules of practice unless such decision is waived.

It is further ordered, That in the event registrant does not appear personally or through a representative at the time and place herein set or as otherwise ordered, the Hearing Room Clerk shall file with the Records Officer of the Commission a written statement to that effect and thereupon the Commission will take the record under advisement for decision.

This order and notice shall be served on registrant personally or by registered mail forthwith, and published in the FEDERAL REGISTER not later than fifteen (15) days prior to January 29, 1951.

In the absence of an appropriate waiver, no officer or employee of the Commission engaged in the performance of Investigative or prosecuting functions in this or any factually related proceeding will be permitted to participate or advise in the decision upon the matter except as witness or counsel in proceedings held pursuant to notice. Since this proceeding is not "rule making" within the meaning of section 4 (c) of the Administrative Procedure Act, it is not deemed to be subject to the provisions of the section delaying the effective date of any final Commission action.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F. R. Doc. 50-12494; Filed, Dec. 29, 1950; 8:48 a. m.]

SELECTIVE SERVICE SYSTEM

ORDER FIXING DATES FOR SPECIAL REGISTRATION

By virtue of the authority vested in me by paragraph number 4 of Proclamation No. 2906 issued by the President on October 6, 1950 (15 F. R. 6847), and in furtherance of the purposes of that proclamation which provided for the special registration of male persons in certain medical, dental, and veterinary categories and of Proclamation No. 2915 [1] of December 27, 1950, which exempted from such registration at this time certain aliens and certain members of the armed forces, I, Lewis B. Hershey, Director of Selective Service, hereby fix Monday, the 15th day of January, 1951, between the hours of 8 a. m. and 5 p. m. for the special registration in the several States of the United States, the District of Columbia, the Territories of Alaska and Hawaii, Puerto Rico and the Virgin Islands of the following persons:

Every male person, other than persons exempted by Proclamation No. 2915 of December 27, 1950, who has not already registered under Proclamation No. 2906 of October 6, 1950, and who, on the 15th day of January, 1951, (1) shall have received from a school, college, university, or similar institution of learning, one or more of the degrees of bachelor of medicine, doctor of medicine, doctor of dental surgery, doctor of dental medicine, doctor of veterinary surgery, and doctor of veterinary medicine, (2) is within any of the several States of the United States, the District of Columbia, the Territory of Alaska, the Territory of Hawaii, Puerto Rico, or the Virgin Islands, (3) is not a member of any reserve component of the armed forces of the United States, and (4) shall not have attained the fiftieth anniversary of the day of his birth.

Proclamation No. 2915 of December 27, 1950, exempts from special registration until otherwise directed by the President by proclamation (1) commissioned officers, warrant officers, pay clerks, enlisted men, and aviation cadets of the Regular Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, the Coast and Geodetic Survey, and the Public Health Service, and (2) aliens who are residing in the United States and have not declared their intention of becoming citizens of the United States and who are also in one of the following categories: (a) alien students admitted under subdivision (e) of section 4 of the Immigration Act approved May 26, 1924, as amended, (b) aliens recognized as diplomatic, consular, military or civilian officials or employees of a foreign government and members of their families, (c) aliens who are officials or employees of a public international organization recognized under the International Organizations Immunities Act, approved December 29, 1945 (59 Stat. 669), and members of their families, (d) aliens who have entered the United States and remain therein pursuant to the provisions of section 11 of the Agreement between the United Nations and the United States of America regarding the Headquarters of the United Nations, as approved in Public Law 357, 80th Congress (61 Stat. 756), (e) aliens who are nationals of a country with which there is in effect a treaty or international agreement exempting its nationals from military service while they are within the United States, or (f) other aliens whose admission to the United States is for a temporary stay only.

Each person referred to above who is eligible for registration under this order is required to and shall on Monday, the 15th day of January, 1951, between the hours of 8 a. m. and 5 p. m. present himself for and submit to registration before a duly designated registration official or selective service local board having jurisdiction in the area in which he has his permanent home or in which he may happen to be on that day.

Persons otherwise eligible for registration under this order but who receive any of the degrees above referred to after January 15, 1951, shall be registered on the day they receive any such degree, or within five days thereafter.

Persons otherwise eligible for registration under this order but who enter any of the several States of the United States, the District of Columbia, the Territory of Alaska, the Territory of Hawaii, Puerto Rico, or the Virgin Islands after January 15, 1951, shall be registered on the day of such entrance, or within five days thereafter.

A person subject to registration under this order who, because of circumstances beyond his control, is unable to present himself for and submit to registration during the hours of the day or any of the days fixed for registration shall do so as soon as possible after the cause for such inability ceases to exist.

Every person subject to registration under this order who has registered in accordance with Proclamation No. 2799 of July 20, 1948, issued under the Selective Service Act of 1948, as amended, and the regulations prescribed thereunder, shall, notwithstanding such registration, present himself for and submit to registration as required by this order.

The duty of any person to present himself for and submit to registration in accordance with Proclamation No. 2799 of July 20, 1948, issued under the Selective Service Act of 1948, as amended, and the regulations prescribed thereunder, shall not be affected by this order.

Every person subject to registration under this order is required to familiarize himself with the rules and regulations governing such registration and to comply therewith.

LEWIS B. HERSHEY,
Director of Selective Service.

DECEMBER 28, 1950.

[F. R. Doc. 50-12318; Filed, Dec. 28, 1950; 4:50 p. m.]

[1] *Supra.*

DEPARTMENT OF JUSTICE

Office of Alien Property

AUTHORITY: 40 Stat. 411, 55 Stat. 839, Pub. Laws 322, 671, 79th Cong., 60 Stat. 50, 925; 50 U. S. C. and Supp. App. 1, 616; E. O. 9193, July 6, 1942, 3 CFR, Cum. Supp., E. O. 9567, June 8, 1945, 3 CFR, 1945 Supp., E. O. 9788, Oct. 14, 1946, 11 F. R. 11981.

[Vesting Order 16413]

ANNA AND FRIDRICH NEFF

In re: Rights of Anna Neff and Fridrich Neff under a contract of insurance. File No. D-28-10909-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Anna Neff and Fridrich Neff, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 7 237 399 A issued by the Metropolitan Life Insurance Company, New York, New York, to Anna Neff, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid Metropolitan Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Anna Neff or Fridrich Neff, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12459; Filed, Dec. 28, 1950; 8:52 a. m.]

[Vesting Order 16415]

SHIGEO AND JUJIRO OTSUKI

In re: Rights of Shigeo Otsuki and Jujiro Otsuki under a contract of insurance. File No. F-39-5665-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Shigeo Otsuki and Jujiro Otsuki, whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 1,555,160 issued by the Sun Life Assurance Company of Canada, Montreal, Quebec, Canada, to Shigeo Otsuki, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid Sun Life Assurance Company of Canada together with the right to demand, enforce, receive and collect the same (including without limitation the right to proceed for collection against branch offices and legal reserves maintained in the United States), is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Shigeo Otsuki or Jujiro Otsuki, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12460; Filed, Dec. 28, 1950; 8:52 a. m.]

[Vesting Order 16418]

FRIEDRICH RAMPENDAHL

In re: Rights of Friedrich Rampendahl under insurance contract. File No. F-28-24406-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Friedrich Rampendahl, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the net proceeds due or to become due to Friedrich Rampendahl under a contract of insurance evidenced by policy No. 6,024,081A, issued by the Metropolitan Life Insurance Company, New York, New York, to Friedrich Rampendahl, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of Anna Rampendahl, a resident of the United States, and of the aforesaid Metropolitan Life Insurance Company, together with the right to demand, enforce, receive and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12461; Filed, Dec. 28, 1950; 8:52 a. m.]

[Vesting Order 16260]

EUGEN ROESSLE

In re: Rights of Eugen Roessle under insurance contracts. Files Nos. F-28-24415-H-1, 2, 3, 4, 5.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Eugen Roessle, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the net proceeds due or to become due under contracts of insurance evidenced by policies Nos. 92 338 194, 91 526 430, 98 490 703, 77 544 877, and 45 074 M, issued by the Metropolitan Life Insurance Company, New York, New York, to Eugen Roessle, together with the right to demand, receive and collect said net proceeds.

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 7, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General
Director, Office of Alien Property.

[F. R. Doc. 50-12524; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16263]

MARTA SCHACHT

In re: Rights of Marta Schacht under contracts of insurance. Files Nos. F-28-26592 H-1 and F-28-26592 H-2.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Marta Schacht, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the net proceeds due or to become due under contracts of insurance evidenced by policies 553584 and 583904, issued by The Guardian Life Insurance Company of America, New York, New York, to Ernst Friedrich Schacht, together with the right to demand, receive and collect said net proceeds,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 7, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12525; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16266]

OTTILIA E. SCHINDLER

In re: Rights of Ottilia E. Schindler under insurance contract. File No. D-28-10718 H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Ottilia E. Schindler, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the net proceeds due or to become due to Ottilia E. Schindler under a contract of insurance evidenced by Policy No. 6 347 774, issued by The Prudential Insurance Company of America, Newark, New Jersey, to Josef C. Schindler, together with the right to demand, receive and collect said net proceeds,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 7, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12526; Filed Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16267]

ELISE SCHNEIDER

In re: Rights of Elise Schneider under insurance contract. File No. D-28-7739-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Elise Schneider, whose last known address is Germany is a resident of Germany and a national of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by policy No. 18 339, issued by the Workmen's Benefit Fund, Brooklyn, New York, to Anna Fox, together with the right to demand, receive and collect said net proceeds,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 7, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12527; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16269]

RICHARD SCHULZ

In re: Rights of Richard Schulz under contract of insurance. File No. F-28-24887-H-2.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Richard Schulz, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 16813 NW 200 issued by The Travelers Insurance Company, Hartford, Connecticut, to Walter Albert Schulz, together with the right to demand, receive and collect said net proceeds,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 7, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12528; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16309]

LEOPOLD FULDE

In re: Stock owned by Leopold Fulde. F-28-31074-D-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Leopold Fulde, whose last known address is 20A Mellendorf, Hanover, Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the property described as follows: Four (4) shares of $25.00 par value common capital stock of Standard Oil Company (Indiana), 910 South Michigan Avenue, Chicago 80, Illinois, a corporation organized under the laws of the State of Indiana, evidenced by certificate numbered D-249570, registered in the name of Leopold Fulde, together with all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12529; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16312]

FREDERICK HEINKEN

In re: Debt owing to the personal representatives, heirs, next of kin, legatees and distributees of Frederick Heinken, also known as Herman Frederick Ludwig Heinken, deceased. F-28-3619-C-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That the personal representatives, heirs, next of kin, legatees and distributees of Frederick Heinken, also known as Herman Frederick Ludwig Heinken, deceased, who there is reasonable cause to believe are residents of Germany, are nationals of a designated enemy country (Germany);

2. That the property described as follows: That certain debt or other obligation of the State Employees' Retirement System of New Jersey, Room 413, First Mechanics National Bank Building, Trenton, New Jersey, arising out of a pension fund held by the aforesaid State Employees' Retirement System of New Jersey in the name of William Heinken, in the amount of $2,505.05 as of October 11, 1949, together with any and all accruals thereto, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by the personal representatives, heirs, next of kin, legatees and distributees of Frederick Heinken, also known as Herman Frederick Ludwig Heinken, deceased, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the personal representatives, heirs, next of kin, legatees and distributees of Frederick Heinken, also known as Herman Frederick Ludwig Heinken, deceased, are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12530; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16313]

HELM BROS. LTD.

In re: Bonds owned by and debt owing to Messrs. Helm Bros. Ltd., also known as Helm Bros. Ltd. F-39-419-A-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Helm Bros. Ltd., also known as Messrs. Helm Bros. Ltd., the last known address of which is 48 Yamashita-Cho, Yokohama, Japan, is a corporation which has or, since the effective date of Executive Order 8389, as amended, has had its principal place of business in Yokohama, Japan, and is a national of a designated enemy country (Japan);

2. That the property described as follows:

a. Those certain bearer bonds described in Exhibit A, attached hereto and by reference made a part hereof, and presently in the custody of the Guaranty Trust Company of New York, 140 Broadway, New York 15, New York, in an account for Messrs. Helm Bros. Ltd., numbered FC 11164, together with any and all rights thereunder and thereto, and,

b. That certain debt or other obligation owing to Helm Bros. Ltd., also known as Messrs. Helm Bros. Ltd., by the Guaranty Trust Company of New York, 140 Broadway, New York 15, New York, arising out of a custody cash account, entitled Messrs. Helm Bros. Ltd., numbered XC 11164, maintained with the aforesaid company, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by Messrs. Helm Bros. Ltd., also known as Helm Bros. Ltd., the aforesaid national of a designated enemy country (Japan); and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

EXHIBIT A—BONDS

Description of issue	Bond Numbers	Face value
Government of the Dominion of Canada Gold Bonds 4 percent, due 1960.	M 3462, 85484/5, 97688/90, 32480/5	[1] $1,000
Japanese Imperial Government Extended Loan of 1950 Sinking Fund Gold Bonds, 5½ percent, due 1965.	47003, 44256, 44254/5, 21290, 21292, 21281/91, 12056/7, 43725/29, 18868/77, 44253, 47005, 25551/4.	[1] 1,000
Tokyo Japan Extended Loan 1927 Sinking Fund Gold Bonds, 5½ percent, due 1961.	7049, 12217/21, 14110/14, 14922, 15246, 15518, 16244/8, 17439/40, 11077/8, 8885, 3790, 3788, 3787, 15244, 11712, 6624, 13994/7, 6613, 3789, 2446/7, 554/5, 7149, 12981, 14516, 15880, 16408/9 14772, 1339, 12647, 6525, 2040, 7564, 7563, 1423/5, 18229, 3012, 20259, 5720, 5719, 110/111, 849/51, 859/61, 2015, 2102/3, 2029, 3143, 3413, 6333/4, 7188, 7493/4.	[1] 1,000
Yokohama Extension Loan of 1926 Sinking Fund Gold Bonds, 6 percent, due 1961.	11169, 7577/8, 7580/1, 8286/1, 3792, 19152, 14321	[1] 1,000
Oriental Development Co., Ltd., Extension Loan Gold Debenture Guaranteed, 5½ percent, due 1958.	M 14288/92, 2516/20, 8634/5, 3175, 748/9, 5070/1, 16306/8, 10239, 13122/4, 10170, 15426/30, 3001/5, 8441, 17519/20, 17028, 15115, 8440, 18272, 1343, 4892, 5550, 16154/5, 5364, 2753, 15929.	[1] 1,000
Taiwan Elec. Power Co., Ltd., Sinking Fund Gold Bond, 5½ percent, due 1971.	13752/71	[1] 1,000
Tokyo Electric Light Co., Ltd., 1st Mortgage Dollar Series Gold Bond, 6 percent, due 1953.	34166/8, 38621, 38177, 00644/8	[1] 1,000

[1] Each.

[F. R. Doc. 50-12531; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16317]

KURT KNAUTH

In re: Bank account and stock owned by Kurt Knauth. F-28-30826-E-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Kurt Knauth, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the property described as follows:

a. That certain debt or other obligation of The Matinecock Bank of Locust Valley, Locust Valley, New York, arising out of a savings account, account number 4941, entitled Kurt Knauth, and any and all rights to demand, enforce and collect the same, and

b. American Depositary Receipt numbered OF 100094, registered in the name of Kurt Knauth, issued by Guaranty Trust Company of New York for ten (10) shares of ordinary registered capital stock of the Ford Motor Company Limited, of England, and presently in the custody of Karl Knauth, Bayville Road, Locust Valley, New York, together with all rights thereunder and thereto, and

c. American Depositary Receipt numbered PF 13155, registered in the name of Kurt Knauth, issued by the Guaranty Trust Company of New York for ten (10) shares of 4½ percent preferred capital stock of the Ford Motor Company Limited, of England, and presently in the custody of Karl Knauth, Bayville Road, Locust Valley, New York, together with all rights thereunder and thereto,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12532; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16318]

MARTHA M. KOEHN AND WILHELM H. KOEHN

In re: Bank account and securities owned by Martha M. Koehn, also known as Martha Marie Emilie Friedericke Koehn and as Martha Marie Koehn and Wilhelm H. Koehn. F-28-14784-A-1; C-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Martha M. Koehn, also known as Martha Marie Emilie Friedericke Koehn and as Martha Marie Koehn, and Wilhelm H. Koehn, whose last known address is 265 Volhstr., Volksdorfe, Hamburg, Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the property described as follows:

a. That certain debt or other obligation owing to Martha M. Koehn, also known as Martha Marie Emilie Friedericke Koehn and as Martha Marie Koehn, by Lake View Trust and Savings Bank, Lincoln and Belmont Avenues, Chicago, Illinois, arising out of a savings account, account numbered 242785, maintained at the aforesaid bank, and any and all rights to demand, enforce and collect the same,

b. Twelve (12) shares of capital stock of American Telephone and Telegraph Company, 195 Broadway, New York 7,

New York, a corporation organized under the laws of the State of New York, evidenced by certificates numbered PN-57446 for 6 shares, L239072 for 1 share, M126719 for 2 shares and SN78705 for 3 shares, registered in the name of Martha Koehn, and presently in the custody of Fred G. Schulze, 822 Wrightwood Avenue, Chicago 14, Illinois, together with all declared and unpaid dividends thereon,

c. Those certain securities issued by I. G. Farben Industrie A. G., Frankfort A/M Germany, evidenced by two certificates each of Reichsmark 200 face value, numbered 681190 Lit. B and 1236048 Lit. B, registered in the name of Martha Koehn, and presently in the custody of Fred C. Schulze, 822 Wrightwood Avenue, Chicago 14, Illinois, together with all declared and unpaid dividends thereon,

d. All property of any nature whatsoever owned by Martha M. Koehn, also known as Martha Emilie Friedericke Koehn and as Martha Marie Koehn, now or formerly located in a safe deposit box, box numbered 42074, leased in the name of Charlotte Schulze, now deceased, from the National Safe Deposit Co., First National Bank Building, Chicago, Illinois, with right of access by Fred C. Schulze, 822 Wrightwood Avenue, Chicago 14, Illinois, and all rights and interests of said Martha M. Koehn, evidenced or represented thereby,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by Martha M. Koehn, also known as Martha Marie Emilie Friedericke Koehn and as Martha Marie Koehn, the aforesaid national of a designated enemy country (Germany);

3. That the property described as follows: One (1) share of capital stock of North German Lloyd (Norddeutscher Lloyd American Shares) a corporation organized under the laws of Germany, evidenced by a certificate numbered NF618, registered in the name of Wilhelm H. Koehn, and presently in the custody of Fred C. Schulze, 822 Wrightwood Avenue, Chicago 14, Illinois, together with all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by Wilhelm H. Koehn, the aforesaid national of a designated enemy country (Germany);

4. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany);

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12533; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16323]

SHINICHI MATSUBARA

In re: Stock owned by Shinichi Matsubara. F-39-6566-D-1; E-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Shinichi Matsubara, whose last known address is Nagasaki, Japan, is a resident of Japan and a national of a designated enemy country (Japan);

2. That the property described as follows: Twelve and one-half (12½) shares of no par value (new) capital stock of Standard Brands Incorporated, a corporation organized under the laws of the State of Delaware, evidenced by certificate number CO 325538, dated April 22, 1935, for fifty (50) shares of no par value (old) common capital stock of the aforesaid corporation, and presently in the custody of The Sumitomo Bank of Seattle, Room 1210-1411 Fourth Avenue Building, Seattle, Washington, together with all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12534; Filed, Dec. 29, 1950; 8:54 a. m.]

[Vesting Order 16326]

TOKUZO NAKASHIMA

In re: Debts owing to Tokuzo Nakashima, also known as T. Nakashima, and Nobuo Shigemichi. D-39-1459.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Takuzo Nakashima, also known as T. Nakashima, and Nobuo Shigemichi, each of whose last known address is Japan are residents of Japan and nationals of a designated enemy country (Japan);

2. That the property described as follows: Those certain debts or other obligations owing to Tokuzo Nakashima also known as T. Nakashima and Nobuo Shigemichi by Mutual Credit Society, c/o Mr. Fred J. Fujioka, 3644 East Third Street, Los Angeles 33, California, representing funds held by said Mutual Credit Society for distribution to said Tokuzo Nakashima, also known as T. Nakashima, and Nobuo Shigemichi, together with any and all accruals thereto and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall

have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12535; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16328]

HIROSHI FRED OKAMOT

In re: Cash owned by Hiroshi Fred Okamot F-39-6701-E-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Hiroshi Fred Okamoto, whose last known address is Japan, is a resident of Japan and a national of a designated enemy country (Japan);

2. That the property described as follows: Cash in the sum of $153.95, presently in the possession of the Treasury Department of the United States in Trust Fund Account, Symbol 158915, "Deposits, Funds of Civilian Internees and Prisoners of War," in the name of Hiroshi Fred Okamoto, and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by Hiroshi Fred Okamoto, the aforesaid national of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12536; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16331]

RUHRWOHNUNGSBAU-AKTIENGESELLSCHAFT

In re: Bank accounts owned by Ruhrwohnungsbau-Aktiengesellschaft, also known as Ruhr Housing Corporation. F-28-23682-E-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Ruhrwohnungsbau-Aktiengesellschaft, also known as Ruhr Housing Corporation, the last known address of which is 9 Katharinenstrasse, Dortmund, Germany, is a corporation, partnership, association or other business organization, organized under the laws of Germany, and which has or, since the effective date of Executive Order 8389, as amended, has had its principal place of business in Germany and is a national of a designated enemy country (Germany);

2. That the property described as follows:

a. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Coupon Deposit Account, entitled "Ruhr Housing Corporation 6½% Bonds due 1958", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

b. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Redemption Account, entitled "Ruhr Housing Corporation 6½% Bonds due 1958", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same, and

c. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Service Fund Account, entitled "Ruhr Housing Corporation 6½% Bonds due 1958", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Ruhrwohnungsbau - Aktiengesellschaft, also known as Ruhr Housing Corporation, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12538; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16330]

RUHRGAS AKTIENGESELLSCHAFT

In re: Bank account owned by Ruhrgas Aktiengesellschaft, also known as Ruhr Gas Corporation. F-28-6885-E-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Ruhrgas Aktiengesellschaft, also known as Ruhr Gas Corporation, the last known address of which is Herwarthstrasse 60, Essen, Germany, is a corporation, partnership, association or other business organization, organized under the laws of Germany, and which has or, since the effective date of Executive Order 8389, as amended, has had its principal place of business in Germany and is a national of a designated enemy country (Germany);

2. That the property described as follows: That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Coupon Deposit Account, entitled "Ruhr Gas Corporation 6½% Bonds due 1953", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Ruhrgas Aktiengesellschaft, also known as Ruhr Gas Corporation, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12537; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16336]

VEREINIGTE STAHLWERKE AKTIENGESELLSCHAFT

In re: Bank accounts owned by Vereinigte Stahlwerke Aktiengesellschaft, also known as United Steel Works Corporation. F-28-4579-E-2.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. Vereinigte Stahlwerke Aktiengesellschaft, also known as United Steel Works Corporation, the last known address of which is Duesseldorf, Germany, is a corporation, partnership, association or other business organization, organized under the laws of Germany, and which has or, since the effective date of Executive Order 8389, as amended, has had its principal place of business in Germany and is a national of a designated enemy country (Germany);

2. That the property described as follows:

a. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Coupon Deposit Account, entitled "Rheinelbe Union 7% bonds due 1946", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

b. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Coupon Deposit Account, entitled "United Steel Works Corporation 6½% Debentures due 1947", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

c. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Coupon Deposit Account, entitled "United Steel Works Corporation 6½% Bonds Series A & Series C due 1951", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

d. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Redemption Account, entitled "United Steel Works Corporation 6½% Bonds Ser. A due 1951", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

e. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Service Fund Account, resulting from unapplied sinking fund monies, entitled "United Steel Works Corporation 6½% Bonds Series C due 1951", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

f. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Coupon Deposit Account, entitled "Gelsenkirchen Mining Corporation 6% Bonds due 1954", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same, and

g. That certain debt or other obligation of Dillon, Read & Co., 28 Nassau Street, New York, New York, arising out of a Special Account, entitled "Wodan-Handel Maatschappij-Rotterdam", maintained with the aforesaid Dillon, Read & Co., and any and all rights to demand, enforce and collect the same,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Vereinigte Stahlwerke Aktiengesellschaft, also known as United Steel Works Corporation, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12539; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16339]

FRANK X. WIETZEL

In re: Stock owned by Frank X. Wietzel. F-28-85-D-4.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Frank X. Wietzel, whose last known address is Langenhardstrasse 1, Freiburg, Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the property described as follows: All rights and interests evidenced or represented by American Depositary Receipts, issued by Guaranty Trust Company, 140 Broadway, New York, New York, for two hundred (200) shares of 10 Shillings Par Value, Ordinary Registered Capital Stock of British Celanese, Limited, London, England, numbered 5524 and 5525, registered in the name of Frank X. Wietzel, together with any and all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12540; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16342]

HEDWIG HESS

In re: Estate of Hedwig Hess, deceased. File No. D-28-8770; E. T. sec. 10647.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Gottfried Straub and Amelie Hess whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That all right, title, interest and claim of any kind or character whatsoever of the persons identified in subparagraph 1 hereof and each of them, in and to the Estate of Hedwig Hess, deceased, is property payable or deliverable to, or claimed by the aforesaid nationals of a designated enemy country (Germany);

3. That such property is in the process of administration by Ben H. Brown, as administrator, acting under the judicial supervision of the Superior Court of the State of California, County of Los Angeles;

and it is hereby determined:

4. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 11, 1950.

For the Attorney General.

[SEAL] PAUL V. MYRON,
Deputy Director,
Office of Alien Property.

[F. R. Doc. 50-12542; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16341]

MRS. I. TH. VON WITZLEBEN-WILKENS

In re: Stock owned by Mrs. I. Th. von Witzleben-Wilkens. F-28-31082.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Mrs. I. Th. von Witzleben-Wilkens on or since the effective date of Executive Order 8389, as amended, and on or since December 11, 1941, has been a resident of Germany, and is a national of a designated enemy country (Germany);

2. That the property described as follows:

a. Ten (10) shares of capital stock par value $50.00 of the Anaconda Copper Mining Company, evidenced by a certificate No. E 195696, registered in the name of N. V. Maatschappy tot Beheer van het Administratiekantoor van Amerikaansche Fondsen, opgerigt door Broes & Grosman Ten Have & Van Essen en Jarman & Zoonen te Amsterdam, which certificate is presently in the custody of the Guaranty Trust Company of New York, 140 Broadway, New York 15, New York, together with all declared and unpaid dividends thereon,

b. Twenty (20) shares of 7% cumulative preferred stock, par value $100.00, of the Bethlehem Steel Corporation evidenced by certificates numbered S-32707 and S-32708, registered in the name of N. V. Maatschappy tot Beheer van het Administratiekantoor van Amerikaansche Fondsen, opgerigt door Broes & Grosman Ten Have & Van Essen en Jarman & Zoonen te Amsterdam, which certificates are presently in the custody of the Guaranty Trust Company of New York, 140 Broadway, New York 15, New York, together with all declared and unpaid dividends thereon, and

c. Ten (10) shares of capital stock, par value $25.00, of Commonwealth Edison Company evidenced by certificate numbered 3182 registered in the name of N. V. Kantoor tot Uitgifte van Certificaten "CEBUWA" Amsterdam, which certificate is presently in the custody of the Guaranty Trust Company of New York, 140 Broadway, New York 15, New York, together with all declared and unpaid dividends thereon,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by Mrs. I. Th. von Witzleben-Wilkens, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 8, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12541; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16357]

JOSEPH BOETTCHER

In re: Rights of Joseph Boettcher under insurance contract. File No. D-28-10904-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Joseph Boettcher, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by policy No. 7300 GLH, Serial CH 103, issued by the Metropolitan Life Insurance Company, New York, New York, to Rudolph Boettcher, together with the right to demand, receive and collect said net proceeds,

is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, the aforesaid national of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12543; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16360]

EMMI ZAMPONI CLAUSS, ET AL.

In re: Rights of Emmi Zamponi Clauss, et al., under a contract of insurance. File No. F-28-24784-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Emmi Zamponi Clauss, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the domiciliary personal representatives, heirs, next of kin, legatees, and distributees, names unknown, of Emmi Zamponi Clauss, who there is rea-

sonable cause to believe are residents of Germany, are nationals of a designated enemy country (Germany);

3. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 60200777 issued by The Prudential Insurance Company of America, Newark, New Jersey, to Emmi Zamponi Clauss, together with the right to demand, receive, and collect said net proceeds, is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account or, or owing to, or which is evidence of ownership or control by Emmi Zamponi Clauss or the domiciliary personal representatives, heirs, next of kin, legatees, and distributees, names unknown, of Emmi Zamponi Clauss, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

4. That to the extent that the person named in subparagraph 1 hereof and the domiciliary personal representatives, heirs, next of kin, legatees and distributees, names unknown, of Emmi Zamponi Clauss, are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12544; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16361]

FRANZ DAHLKE

In re: Estate of Franz Dahlke, deceased. File No. D-28-11611; E. & T. sec. 15823.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. Ernestine Dahlke and Agnes Dahlke, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That all right, title, interest and claim of any kind or character whatsoever of the persons named in subparagraph 1 hereof, and each of them, in and to the estate of Franz Dahlke, deceased, is property payable or deliverable to, or claimed by the aforesaid nationals of a designated enemy country (Germany);

3. That such property is in the process of administration by Robert G. Clostermann, as administrator, acting under the judicial supervision of the County Court of Gilliam County, Oregon;

and it is hereby determined:

4. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12545; Filed, Dec. 29, 1950; 8:55 a. m.]

[Vesting Order 16362]

PAUL DAHLKE

In re: Estate of Paul Dahlke, deceased. File No. D-28-11610; E. & T. sec. 15822.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Paul Reinhold Dahlke, Helene Schulz, Agnes Dahlke and Klara Kreiss, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That all right, title, interest and claim of any kind or character whatsoever of the persons named in subparagraph 1 hereof, and each of them, in and to the estate of Paul Dahlke, deceased, is property payable or deliverable to, or claimed by the aforesaid nationals of a designated enemy country (Germany);

3. That such property is in the process of administration by Robert G. Clostermann as administrator, acting under the judicial supervision of the County Court of Gilliam County, Oregon;

and it is hereby determined:

4. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12546; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16419]

ARNOLF P. REHBOCK ET AL.

In re: Rights of Arnolf P. Rehbock et al., under insurance contracts. Files No. D-28-5313-H-1, H-2.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Arnolf P. Rehbock, Liselotte H. Rehbock, Margaret K. Rehbock and Theodore Rehbock, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under contracts of insurance evidenced by policies No. 2526744 and 2713988, issued by the John Hancock Mutual Life Insurance Company, Boston, Massachusetts, to Arnolf P. Rehbock, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contracts of insurance except those of the aforesaid John Hancock Mutual Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Arnolf P. Rehbock or Liselotte H. Rehbock, Margaret K. Rehbock and Theodore Rehbock, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the

national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12547; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16419]

KURT HERMANN GOTTLIEB RICHTER ET AL.

In re: Rights of Kurt Hermann Gottlieb Richter et al. under insurance contract. File No. F-28-3395-H-2.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Kurt Hermann Gottlieb Richter and Helga B. H. Richter, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by policy No. 739,552, issued by the Phoenix Mutual Life Insurance Company, Hartford, Connecticut, to Kurt Hermann Gottlieb Richter, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid Phoenix Mutual Life Insurance Company together with the right to demand, enforce, receive, and collect the same, is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by, Kurt Hermann Gottlieb Richter or Helga B. H. Richter, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12548; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16422]

FRANZISKA RITZLER

In re: Trust under Deed dated October 2, 1934, of Franziska Ritzler. File No. D-28-8331; E. T. sec. No. 9635.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Katie Becker, Marianna Becker and Elizabeth Lehmann, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the issue, names unknown, of Franz Becker, deceased, of Katie Becker and of Marianna Becker, who there is reasonable cause to believe are residents of Germany, are nationals of a designated enemy country (Germany);

3. That the property described as follows:

(a) All right, title, interest and claim of any kind or character whatsoever of the persons identified in subparagraphs 1 and 2 hereof, not heretofore vested by Vesting Order No. 3182, in and to and arising out of or under that certain trust agreement dated October 2, 1934, by and between Franziska Ritzler, grantor, and Girard Trust Company and James A. McQuail, Jr., trustees, and

(b) All property in the possession, custody or control of Girard Trust Company and James A. McQuail, Jr., as trustees under that certain trust agreement dated October 2, 1934, by and between Franziska Ritzler, grantor, and Girard Trust Company and James A. McQuail, Jr., trustees, including particularly but not limited to the sum of $8,423.34 as of October 30, 1950, together with any and all accruals thereto,

is property payable or deliverable to, or claimed by, the aforesaid nationals of a designated enemy country (Germany);

4. That such property is in the process of administration by Girard Trust Company and James A. McQuail, Jr., as trustees, acting under the judicial supervision of the Orphans' Court of Philadelphia County, Philadelphia, Pennsylvania;

and it is hereby determined:

5. That to the extent that the persons named in subparagraph 1 hereof and the issue, names unknown, of Franz Becker, deceased, of Katie Becker and of Marianna Becker are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, subject to all lawful fees and disbursements of Girard Trust Company and James A. McQuail, Jr., as trustees under that certain trust agreement dated October 2, 1934, by and between Franziska Ritzler, grantor, and Girard Trust Company and James A. McQuail, Jr., trustees,

All such property so vested shall be held, used, administered, liquidated, sold, or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12549; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16425]

HANS F. AND GRACE B. RUDMANN

In re: Rights of Hans F. Rudmann and Grace B. Rudmann under insurance contract. File No. F-28-27989-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Hans F. Rudmann and Grace B. Rudmann, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 7 303 422 issued by The Prudential Insurance Company of America, Newark, New Jersey, to Hans F. Rudmann, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid The Prudential Insurance Company of America together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Hans F. Rudmann or Grace B.

Rudmann, the aforesaid nationals of a designated enemy country (Germany); and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12550; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16426]

SAKAYE SASAKI ET AL.

In re: Rights of Sakaye Sasaki et al., under insurance contract. File No. F-39-4511 H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Sakaye Sasaki and Tokuichi Sasaki, whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 17 211 990, issued by the New York Life Insurance Company, New York, New York, to Sakaye Sasaki, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid New York Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Sakaye Sasaki or Tokuichi Sasaki, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General
Director, Office of Alien Property.

[F. R. Doc. 50-12551; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16428]

KARL AND WILMA E. SCHENK

In re: Rights of Karl Schenk and Wilma E. Schenk under a contract of insurance. File No. F-28-22705-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Karl Schenk and Wilma E. Schenk, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 13 189 161 issued by the New York Life Insurance Company, New York, New York, to Karl Schenk, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid New York Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Karl Schenk or Wilma E. Schenk, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12552; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16429]

FRANZ KARL OTTO SCHLEDT ET AL.

In re: Rights of Franz Karl Otto Schledt et al., under insurance contract. File No. F-28-132-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Franz Karl Otto Schledt, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the domiciliary personal representatives, heirs, next of kin, legatees and distributees, names unknown, of Franz Karl Otto Schledt, who there is reasonable cause to believe are residents of Germany, are nationals of a designated enemy country (Germany);

3. That the net proceeds due or to become due under a contract of insurance evidenced by policy No. 4 079 143, issued by the New York Life Insurance Company, New York, New York, to Franz Karl Otto Schledt, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid New York Life Insurance Company, together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Franz Karl Otto Schledt or the domiciliary personal representatives, heirs, next of kin, legatees and distributees, names unknown, of Franz Karl Otto Schledt, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

4. That to the extent that the person named in subparagraph 1 hereof and the domiciliary personal representatives, heirs, next of kin, legatees and distributees, names unknown, of Franz Karl Otto Schledt, are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12553; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16430]

JOHN AND HENRY SCHNACKENBERG

In re: Rights of John Schnackenberg and Henry Schnackenberg under a contract of insurance. File No. F-28-30382-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That John Schnackenberg and Henry Schnackenberg, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 11 229-532 issued by the New York Life Insurance Company, New York, New York, to John Schnackenberg, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid New York Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by John Schnackenberg or Henry Schnackenberg, the aforesaid nationals of a designated enemy country (Germany),

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12554; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16431]

ADOLF E. AND MARIE S. SCHONBERG

In re: Rights of Adolf E. Schonberg and Marie S. Schonberg under insurance contracts. Files No. F-28-134-H-1, H-2.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Adolf E. Schonberg and Marie S. Schonberg, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under contracts of insurance evidenced by policies No. 8 014 643 and 8 274 369, issued by the New York Life Insurance Company, New York, New York, to Adolf E. Schonberg, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contracts of insurance except those of the aforesaid New York Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Adolf E. Schonberg or Marie S. Schonberg, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12555; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16433]

PAUL JOHANNES SCHONFELDER ET AL.

In re: Rights of Paul Johannes Schonfelder et al., under insurance contract. File No. F-28-26897-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Paul Johannes Schonfelder and Elfriede Schonfelder, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 3,227,783 issued by The Mutual Life Insurance Company of New York, New York, New York, to Paul Johannes Schonfelder, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of The Mutual Life Insurance Company of New York together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Paul Johannes Schonfelder or Elfriede Schonfelder, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12556; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16435]

CHARLES AND BERTA MARCELLINA SCHUCHARD

In re: Rights of Charles Schuchard and Berta Marcellina Schuchard under a contract of insurance. File No. F-28-3847-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Charles Schuchard, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That Berta Marcellina Schuchard, who on or since the effective date of Executive Order No. 8389, as amended, and on or since December 11, 1941, has been a resident of Germany, is a national of a designated enemy country (Germany);

(3) That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 2825 103 issued by The Mutual Life Insurance Company of New York, New York, New York, to Charles Schuchard, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid The Mutual Life Insurance Company of New York together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Charles Schuchard or Berta Marcellina Schuchard, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

4. That to the extent that the person named in subparagraph 1 hereof is not within a designated enemy country, the national interest of the United States requires that such person be treated as a national of a designated enemy country (Germany);

5. That the national interest of the United States requires that the said Berta Marcellina Schuchard be treated as a national of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12557; Filed, Dec. 29, 1950; 8:56 a. m.]

[Vesting Order 16436]

FRANZ GEORG AND BERNHARD SCHULTE

In re: Rights of Franz Georg Schulte and Bernhard Schulte under an insurance contract. File No. F-28-30420-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Franz Georg Schulte and Bernhard Schulte, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 338-984 issued by Pan-American Life Insurance Company, New Orleans, Louisiana, to Franz Georg Schulte, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid Pan-American Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Franz Georg Schulte or Bernhard Schulte, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12558; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16448]

CARL THIEME ET AL.

In re: Rights of Carl Thieme et al., under insurance contract. File No. F-28-26613-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Carl Thieme, whose last known address is Germany, is a resident of Germany and a national of a designated enemy country (Germany);

2. That the domiciliary personal representatives, heirs, next of kin, legatees and distributees, names unknown, of Carl Thieme, who there is reasonable cause to believe are residents of Germany, are nationals of a designated enemy country (Germany);

3. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 84541 issued by The Guardian Life Insurance Company of America, New York, New York, to Carl Thieme, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid The Guardian Life Insurance Company of America together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Carl Thieme or the domiciliary personal representatives, heirs, next of kin, legatees and distributees, names unknown, of Carl Thieme, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

4. That to the extent that the person named in subparagraph 1 hereof and the domiciliary personal representatives, heirs, next of kin, legatees and distributees, names unknown, of Carl Thieme, are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or other-

wise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12561; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16438]

YOSHIO AND AI SHIOSAKA

In re: Rights of Yoshio Shiosaka and Ai Shiosaka under a contract of insurance. File No. F-39-1635-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Yoshio Shiosaka and Ai Shiosaka, whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 555,940 issued by The Manufacturers Life Insurance Company, Toronto, Ontario, Canada, to Yoshio Shiosaka, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid The Manufacturers Life Insurance Company together with the right to demand, enforce, receive and collect the same (including without limitation the right to proceed for collection against branch offices and legal reserves maintained in the United States), is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Yoshio Shiosaka or Ai Shiosaka, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12559; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16441]

KANAME ANDREW SUSUKI ET AL.

In re: Rights of Kaname Andrew Susuki, et al., under contract of insurance. File F-39-4992-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Kaname Andrew Susuki, Kiyowo Susuki and Mrs. Teiko Susuki, whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 373931-T issued by the Southwestern Life Insurance Company, Dallas, Texas, to Kiyowo Susuki, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid Southwestern Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Kaname Andrew Susuki, or Kiyowo Susuki or Mrs. Teiko Susuki, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12560; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16449]

JOHANN F. W. THIERMANN

In re: Rights of Johann F. W. Thiermann also known as Hans Thiermann et al. under insurance contract. File No. F-28-2563-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Johann F. W. Thiermann, also known as Hans Thiermann and Hedwig A. Thiermann, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by policy No. 637182, issued by The Mutual Benefit Life Insurance Company, Newark, New Jersey, to Johann F. W. Thiermann, also known as Hans Thiermann, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid The Mutual Benefit Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of or on account of, or owing to, or which is evidence of ownership or control by, Johann F. W. Thiermann, also known as Hans Thiermann or Hedwig A. Thiermann, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12562; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16451]

JOHN TRIPS

In re: In the matter of the estate of John Trips, deceased. File No. D-28-12782; E. & T. sec. 16959.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Anna Katharina Henriette Tauer, also known as Jetta Tauer, Else Raps, Irmgard Benedikt, Klemens Edel, Peter Edel, Elisabeth Edel, Johann Georg Lorenz, Max Lorenz, Katharina Zeiger, and Maria Wolf, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That all right, title, interest and claim of any kind or character whatsoever of the persons named in subparagraph 1 hereof, and each of them, in and to the estate of John Trips, deceased, is property payable or deliverable to, or claimed by the aforesaid nationals of a designated enemy country (Germany);

3. That such property is in process of administration by Mervyn F. Bell, as agent, acting under the judicial supervision of the Superior Court of King County, Washington;

and it is hereby determined:

4. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12564; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16450]

SATORU AND MRS. TOME TOFUKUJI

In re: Rights of Satoru Tofukuji and Mrs. Tome Tofukuji under insurance contract. File No. D-39-19067-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Satoru Tofukuji and Mrs. Tome Tofukuji, whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 1511,146 issued by the Sun Life Assurance Company of Canada, Montreal, Quebec, Canada, to Satoru Tofukuji, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid Sun Life Assurance Company of Canada together with the right to demand, enforce, receive and collect the same (including without limitation the right to proceed for collection against branch offices and legal reserves maintained in the United States), is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Satoru Tofukuji or Mrs. Tome Tofukuji, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12563; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16452]

LUISE AND HARRIET UGI

In re: Rights of Luise Ugi and Harriet Ugi under insurance contract. File No. F-28-22753-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Luise Ugi and Harriet Ugi whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 12 526 991 issued by the New York Life Insurance Company, New York, New York, to Luise Ugi, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid New York Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Luise Ugi or Harriet Ugi, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12565; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16454]

YURINO AND MASAICHI UYESUGI

In re: Rights of Yurino Uyesugi and Masaichi Uyesugi under insurance contract. File No. F-39-4542-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Yurino Uyesugi and Masaichi Uyesugi, whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 15 292 022, issued by the New York Life Insurance Company, New York, New York, to Yurino Uyesugi, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid New York Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Yurino Uyesugi or Masaichi Uyesugi, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12566; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16455]

TADAO AND HIDEO WAKE

In re: Rights of Tadao Wake and Hideo Wake under an insurance contract. File No. F-39-2305-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Tadao Wake and Hideo Wake, whose last known address is Japan, are residents of Japan and nationals of a designated enemy country (Japan);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 4 979 746 issued by the New York Life Insurance Company, New York, New York, to Tadao Wake, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid New York Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Tadao Wake or Hideo Wake, the aforesaid nationals of a designated enemy country (Japan);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Japan).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12567; Filed, Dec. 29, 1950; 8:57 a. m.]

[Vesting Order 16456]

MAX H. WALDHAUSEN ET AL.

In re: Rights of Max H. Waldhausen, et al., under insurance contract. File: F-28-7893-H-1.

Under the authority of the Trading With the Enemy Act, as amended, Executive Order 9193, as amended, and Executive Order 9788, and pursuant to law, after investigation, it is hereby found:

1. That Max H. Waldhausen, Agnes Waldhausen, Maria E. Waldhausen and Hans A. Waldhausen, whose last known address is Germany, are residents of Germany and nationals of a designated enemy country (Germany);

2. That the net proceeds due or to become due under a contract of insurance evidenced by Policy No. 1 925 831 issued by The Northwestern Mutual Life Insurance Company, Milwaukee, Wisconsin, to Max H. Waldhausen, and any and all other benefits and rights of any kind or character whatsoever under or arising out of said contract of insurance except those of the aforesaid The Northwestern Mutual Life Insurance Company together with the right to demand, enforce, receive and collect the same is property within the United States owned or controlled by, payable or deliverable to, held on behalf of, or on account of, or owing to, or which is evidence of ownership or control by Max H. Waldhausen, or Agnes Waldhausen or Maria E. Waldhausen, and Hans A. Waldhausen, the aforesaid nationals of a designated enemy country (Germany);

and it is hereby determined:

3. That to the extent that the persons named in subparagraph 1 hereof are not within a designated enemy country, the national interest of the United States requires that such persons be treated as nationals of a designated enemy country (Germany).

All determinations and all action required by law, including appropriate consultation and certification, having been made and taken, and, it being deemed necessary in the national interest,

There is hereby vested in the Attorney General of the United States the property described above, to be held, used, administered, liquidated, sold or otherwise dealt with in the interest of and for the benefit of the United States.

The terms "national" and "designated enemy country" as used herein shall have the meanings prescribed in section 10 of Executive Order 9193, as amended.

Executed at Washington, D. C., on December 13, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12568; Filed, Dec. 29, 1950; 8:57 a. m.]

VITO AND GIUSEPPE MOLEA

NOTICE OF INTENTION TO RETURN VESTED PROPERTY

Pursuant to section 32 (f) of the Trading With the Enemy Act, as amended, notice is hereby given of intention to return, on or after 30 days from the date of the publication hereof, the following property, subject to any increase or decrease resulting from the administration thereof prior to return, and after adequate provision for taxes and conservatory expenses:

Claimant, Claim No., Property, and Location

Vito Molea, Rome, Italy, Claim No. 38476; Giuseppe Molea, Rome, Italy, Claim No. 36648; $1,598.38 in the Treasury of the United States, one-half thereof to each claimant. All right, title and interest of the Attorney General, acquired pursuant to Vesting Order 495 in and to 160 shares of Corner Mott and Hester Streets, Inc., a New York Corporation, one-half thereof to each claimant.

Executed at Washington, D. C., on December 26, 1950.

For the Attorney General.

[SEAL] HAROLD I. BAYNTON,
Assistant Attorney General,
Director, Office of Alien Property.

[F. R. Doc. 50-12573; Filed, Dec. 29, 1950; 8:57 a. m.]